A framework for process evaluations of psychological interventions

Graves, Helen

Awarding institution:
King's College London

A Framework for Process Evaluations of Psychological Interventions

PhD Thesis

Department of Psychological Medicine, Institute of Psychiatry, King's College London

Helen Graves
Student number: 0644738

Summer 2020

Supervisors:
Professor Khalida Ismail
Dr Kirsty Winkley

Abstract

Background:

Randomised controlled trials are the gold standard for testing whether a new intervention produces change in outcome measures but they do not assess underlying mechanisms of action. Process evaluation is an overarching framework for studying potential mechanisms in complex interventions but is rarely applied. Researchers and funders have increasingly called for the inclusion of process evaluations alongside randomised controlled trials of complex interventions but there is no standardised approach. This has led to wide variation in frameworks and methods used. Psychological interventions are particularly complex as they use the collaboration between patient and provider as the conduit for change. Many psychological interventions are being tested in healthcare settings for people with long-term conditions, such as type 2 diabetes. Patients with type 2 diabetes require intensive daily management and have many psychological problems, which contribute to sub optimal control. The clinical setting for this thesis is the D6 study, which tested whether a nurse led psychological intervention could improve glycaemic control in people with type 2 diabetes compared to an attention control condition. A process evaluation of D6 is conducted using a process evaluation framework derived from the literature.

Aims:

i) To review existing frameworks and methods for conducting process evaluations
ii) To apply the findings of this review to develop a theoretical framework for process evaluations of psychological interventions
iii) To test the face validity of the framework on a nurse-led psychological intervention, the D6 cluster RCT, to improve glycaemic control in T2D.

Methods:

A scoping study described existing frameworks for process evaluation and methods used, informing the development of a 12-component process evaluation framework. The framework was tested on a literature review of process evaluations of psychological interventions designed to improve outcome in T2D, and applied to the D6 cluster RCT, a nurse-led intervention testing whether low-intensity psychological therapy could improve self-management in T2D over 12 months versus attention control.

The D6 process evaluation comprised of processes implicit in the main statistical plan, for example the 'dose' of the intervention received, and three additional studies, which were (i) a fidelity assessment of audiotaped therapy sessions delivered by D6 nurses. Independent raters assessed whether D6 nurses achieved competencies in D6 skills at the start of delivering therapy and compared those skills with nurses in the attention control group; (ii) semi-structured interviews explored D6 patient perspectives on taking part in D6 and assessed barriers and facilitators to participation and; (iii) semi-structured interviews explored D6 nurse perspectives on psychological skills training for the D6 study, and barriers and facilitators to taking part. A thematic analysis approach was used to analyse qualitative data.

Results:

The scoping study showed that the field of process evaluation has developed in a haphazard manner with many different frameworks and methods employed. The literature review showed that most RCTs of psychological interventions in T2D had not reported process evaluations. D6 was not effective at improving glycaemic control. The process evaluation showed that (i) there was no difference between the average 7.42 (intervention) and 8.30 (attention control) doses received (ii) that nurse competency in psychological skills was suboptimal with some evidence of contamination (iii) that some participants perceived extra time with nurses positively but others did not, and some reported that diabetes management was not a priority and (iv) that nurses valued impacting patients' empowerment but lacked confidence to

deliver the therapy. The proposed process evaluation framework showed feasibility during testing.

Conclusion:

The field of process evaluation is under developed and lacks standardised methods. There is a need for a flexible framework that can be applied to meet specific intervention requirements, as guidelines cannot be developed using a ‘one size fits all’ approach. The proposed framework tightened theoretical concepts, identified important mechanisms to explain the negative findings of D6 and will inform future study designs.

Acknowledgements:

I would like to thank the following people for their time and support.

My supervisors Professor Khalida Ismail and Dr Kirsty Winkley have been generous with their expert advice throughout my PhD. Professor Ismail in particular has supported me through some difficult periods and I am very grateful to her. Dr Winkley has also been very supportive, and I would like to thank her for her advice and encouragement.

I would like to thank Professor Stephanie Amiel, Dr Nicole DeZoyza, Dr Daniel Stahl and the rest of the D6 team including in particular Sarah Mann and Chris Turner for their support and endless cups of tea.

I will always be thankful to the National Institute for Health Research who funded the D6 Study and therefore made my PhD possible.

A special thank you goes to the participants of D6, who were so generous with their time, and to the GP practice nurses who took part.

Finally, I would like to thank my family and friends for (many years) of support.

I dedicate this thesis to Chaz and Delia.

Statement of Contribution:

This thesis is embedded within the Diabetes-6 (D6) Study; a National Institute for Health Research (NIHR) Programme Grant funded RCT.

Chief Investigator Professor Stephanie Amiel and Co-Investigator Professor Khalida Ismail designed the D6 Study. The NIHR programme grant manager/NIHR Post-doctoral Fellow was Dr Kirsty Winkley. The clinical psychologist responsible for designing the D6 therapy, and training and supervising general practice nurses was Dr Nicole DeZoysa.

The primary aim was to investigate the association between the D6 intervention and glycaemic control in individuals with poorly controlled type 2 diabetes. I worked on D6 from September 2010 – April 2015 as a Research Assistant. My responsibilities and contributions to D6 were as follows:

Recruitment and follow-up: I recruited patients into the study and contributed to data collection, both at recruitment and follow-up stages, between June 2010 and November 2012.

Data Management: I was responsible, along with other Research Assistants working on D6, for the day-to-day management of data, including paper records and computer databases. I also supported the Principal Investigators in the day-to-day running of D6, for example, covering colleagues on leave, coordinating and collaborating with other researchers in workload management, data management and office management.

Nurses: I was responsible, along with other Research Assistants for managing the nurses recruited into the study including regular visits, phone calls and administrative support.

Presentations: I presented data from Chapter 8 of this thesis at the Diabetes UK Professional Conference 2015, and was awarded the Diabetes UK Psychological Care

Poster Award for an outstanding poster and oral presentation in the area of psychological care.

PhD Design: Although I was not involved in the original design of D6, I lead the formulation of the process evaluation framework that defines this thesis.

The demographic, biomedical and other outcome variables reported in Chapter 5 were routinely collected as part of D6. Dr Daniel Stahl (Department of Biostatistics, Institute of Psychiatry) performed the statistical analysis of D6, including all analysis reported in Chapter 5.

The fidelity data reported in Chapter 6 were collected by Dr Emma Shuttlewood (clinical psychologist, Department of Psychological Medicine, Institute of Psychiatry) and the tapes rated by 2 independent clinical psychologists. I conducted the statistical analysis reported in Chapter 6.

I collected all qualitative data reported in Chapters 7 and 8 and performed the analysis.

Contents:

Tables in This Thesis 15

Figures in This Thesis 15

Abbreviations Used in This Thesis 17

Chapter 1: Context and Aims 19

- Chapter Summary 19
- Introduction 19
- Background 21
- The Need for Process Evaluation 24
- The Medical Research Council's Guidance for Evaluating Complex Interventions 25
- The Current Problem: Lack of Framework 26
- The Setting for This Thesis 30
- The Aims of This Thesis 31
- Overview of the Structure of This Thesis 31

Chapter 2: Type 2 Diabetes 33

- Chapter Summary 33
- Overview of Diabetes 33
- Type 2 Diabetes 34
- Epidemiology of Type 2 Diabetes 36
- Complications of Type 2 Diabetes 36
  - Macro-vascular Complications 36
  - Micro-vascular Complications 37
- Risk Factors 39
- Economic Cost of Diabetes 39
- Management of Type 2 Diabetes 40
- Non-Pharmacological Treatments 41
- Pharmacological Treatments 42
  - Oral Hypoglycaemic Agents 42
  - Insulin 44
- The Clinical Problem of Persistent Suboptimal Glycaemic Control 45

Psychological Problems and Glycaemic Control 45
Can Psychological Therapies Improve Outcome in Type 2 Diabetes? 48
Summary and Conclusions 50
Chapter 3: The Process Evaluation of Complex Interventions 51
Chapter Summary 51
Definition of a Complex Intervention 51
What is Process Evaluation? 53
Formative and Summative Process Evaluation 55
The Purposes of Process Evaluation 57
A Scoping Study of the Evolution of Process Evaluation Theory: 60
Aims: 62
Methods: 62
Data Extraction: 63
Results: 64
A Brief History of Evaluation 64
The Development of the Concept of Process Evaluation 65
Implementation Research 69
Formalising Process Evaluation 71
A Framework for Planning, Designing and Conducting a Process Evaluation 81
The Components of Process Evaluation 82
1. Formative Process Evaluation 82
2. Acceptability and Social Validity 83
3. Recruitment 84
4. Dose Delivered 85
5. Dose Received 86
6. Programme Implementation/Fidelity 86
7. Contamination 87
8. Provider Experience 87
9. Participant Experience 88
10. Context 88
11. Barriers and Facilitators 89
12. Adoption 89
Process Evaluation Methodology 90

Quantitative Measures Used in Process Evaluation 93
Qualitative Measures Used in Process Evaluation 95
Systematic Review (Quantitative or Qualitative) 98
Strengths and Limitations of Scoping Study and Framework Development 103
Summary and Conclusions 104
Chapter 4: Literature Review 106
Chapter Summary 106
Aims 106
Methods 107
Data Extraction 108
Results 109
Components of Process Evaluation Reported 129
Selection and Combination of Methods 137
Discussion 141
Summary of Findings 141
What Did the Process Evaluation Data Tell Us? 143
Strengths and Limitations of This Literature Review 143
Future Research 145
Conclusions 145
Chapter 5: The Diabetes 6 Study 147
Chapter Summary 147
Background and Clinical Problem 147
Role of Psychological Treatments in Management of Type 2 Diabetes 149
Could Health Professionals Deliver Psychological Care in Diabetes? 150
Main Hypothesis 151
Secondary Hypotheses 151
Design and Setting 151
Study Population and Study Criteria 152
Inclusion Criteria 152
Exclusion Criteria 153
Recruitment 153
Randomisation and Allocation Concealment 154
Research Team 154

Baseline Measures 155
Description of Intervention 156
Group 1: Usual Care Attention Control 156
Group 2: Usual Care Plus D6 156
Training of D6 Nurses 157
Adherence to The Protocol 162
Loss to Follow Up and Other Missing Data 162
Statistical Analysis 163
Power Calculation 163
Process Evaluation 164
Results of The D6 Study 165
Protocol Violation 166
Sample Characteristics 169
Results of Process Evaluation Components Recruitment, Dose Delivered and Dose Received 175
Recruitment 175
Dose Delivered and Dose Received 176
Discussion 176
Strengths and Limitations 176
Conclusion 178
Chapter 6: Assessing Fidelity and Competencies of Practice Nurses Delivering Motivational Interviewing and Cognitive Behavioural Therapy to Support Self-Management in Type 2 Diabetes. 179
Chapter Summary 179
Definitions of Fidelity 179
The Rationale for Considering Treatment Fidelity 180
Defining the Concept of Treatment Fidelity 181
Defining Competence 183
The Fidelity Versus Adaptation Debate 185
Measuring Treatment Fidelity 186
Self-Reported Treatment Fidelity 186
Ethnographic Data 187
Rating of Audiotaped Intervention Sessions 187

Assessing Fidelity of the D6 Intervention 188
Aims 188
Methods 188
Design 188
The Training Program in D6 188
Techniques Taught in Motivational Interviewing and Cognitive Behavioural Therapy 189
Techniques Taught in Cognitive Behavioural Therapy 191
Combining Motivational Interviewing and Cognitive Behavioural Therapy 192
Clinical Supervision 192
Assessment of Fidelity to Motivational Interviewing 192
Tools for Measuring Fidelity to Cognitive Behavioural Therapy 194
Sampling Procedure 195
Data Analysis 197
Results 197
Sample Characteristics 197
Inter-rater Reliability 198
Nurse Adherence 199
Nurse Competency 199
Fidelity Analysis 200
Discussion 201
Conclusion 206
Chapter 7: Psychological Skills Training to Support Diabetes Self-Management: Qualitative Assessment of Nurses' Experiences. 207
Chapter Summary 207
Background 207
Aims 210
Methods 210
Rationale for Employing Framework Analysis 212
Reflexivity in Qualitative Research 213
Results 213
Themes 214
1. Positive and Negative Impact of D6 214

2. Professional Boundaries 219
3. Support 220
Discussion 222
Strengths and Limitations 223
Conclusion 225
Chapter 8: Patients' Experiences of Participating in a Randomised Controlled Trial of a Psychological Therapy Designed to Improve Sub-Optimal Glycaemic Control In Type 2 Diabetes: A Qualitative Study 227
Chapter Summary 227
Background 227
Psychological Barriers to Diabetes Self Care 227
Addressing Psychological Barriers to Diabetes Self-care 230
Evaluating Psychological Therapies Delivered in Primary Care 230
Aim 231
Methods 231
The Current Study 231
Rationale for Employing Framework Analysis 234
Reflexivity in Qualitative Research 235
Results 235
Sample Characteristics 236
Themes 239
1: Frequency and Content of Appointments 240
2: Barriers and Facilitators to Behaviour Change 241
3: Positive and Negative Aspects of Nurse Manner 243
4: Reasons for Taking Part 243
Summary of Key Findings 244
Discussion 245
Conclusion 250
Chapter 9: Discussion 251
Overview 251
Aims of this Thesis 251
Summary of Findings 251
Summary of the Process Evaluation of D6 253

Formative Process Evaluation 253
Acceptability and Social Validity 255
Recruitment 255
Dose Delivered 256
Dose Received 256
Programme Implementation/Fidelity 257
Contamination 258
Provider Experience 259
Participant Experience 260
Context 261
Barrier and Facilitators 263
Adoption 263
Overall Assessment of This Process Evaluation Framework 264
Revised Process Evaluation Framework Components 264
Strengths and Limitations 266
The Future of Process Evaluation 275
Realist RCTs 276
Future Process Evaluation Purposes and Methods 278
Future Challenges 280
Conclusion 281
References 283
Appendices 321
Appendix 1: Search Strategy for Scoping Study (MEDLINE via PubMed) 321
Appendix 1 Continued: Search Strategy for Literature Review 323
MEDLINE 324
PsychINFO 327
Cochrane Controlled Trials 331
CINAHL 335
Web of Science 341
Appendix II: MITI Version 3.0 344
Appendix II Continued: BECCI 378
Appendix III: Participant Consent Forms and Information Sheets 380
Appendix IV: Interview Schedules 393

Tables in This Thesis

Table	Content	Page
3.1	Scoping Study Search Terms	63
3.2	Components of Process Evaluation Measured by Most Commonly Cited Frameworks	82
3.3	Process Evaluation Components, Definitions and Potential Quantitative and Qualitative Methodologies	92
4.1	Process Evaluations of Randomised Controlled Trials of Psychological Interventions to Improve Glycaemic Outcome in Patients with Type 2 Diabetes. Phase 1 (1966-2003) and phase 2 (2003-2016)	112
4.2	Components of Process Evaluation Studied by Randomised Controlled Trials Identified for Review	136
4.3	Summary of Methods Used to Conduct Process Evaluations	139
5.1	Summary of Skills Taught in D6 Intervention	158
5.2	Baseline Characteristics of Participants Randomly Assigned to Receive D6 or Standard Care	170
5.3	Results from D6 Primary and Secondary Outcome Measures	174
6.1	Level of Nurse Training in Psychological Techniques	198
6.2	Intraclass Correlation Coefficients for MITI Global Scores and BECCI Practitioner Score	199
6.3	Mean Competency Scores Assessed Post-training and During Intervention	200
6.4	Mean Scores for MITI and BECCI Summary Scales by Treatment Group	202
8.1	Original Sampling Matrix	232
8.2	Sample Characteristics	237
8.3	Sampling Matrix Showing Actual Numbers Recruited	238
8.4	Individual Patient Characteristics Showing Number of D6 Sessions and Interview Data	239
8.5	A Revised Framework for Process Evaluations of Psychological Interventions	265

Figures in This Thesis

Figure	Content	Page
1.1	CONSORT Flow Diagram Reproduced From CONSORT 2010	27
1.2	CONSORT Checklist reproduced from CONSORT 2010	28
2.1	The Pathophysiology of Type 2 Diabetes	34
3.1	Levels of a Complex Intervention at Which Measurable Processes Occur	54
3.2	Stages of Intervention Mapping	58
3.3	The MRC evaluation framework	75
3.4	A framework for Evaluating Complex Interventions	78
3.5	MRC 'key functions' of process evaluation, reproduced from Process Evaluation of Complex Interventions: a Summary of Medical Research Council Guidance	80
3.6	Process Evaluation: A Checklist for Researchers	100
4.1	Flow Chart Showing Studies Identified as Carrying out a Process Evaluation	111
5.1	Recruitment and Randomisation Timeline of D6	167
5.2	CONSORT Flow Diagram for The D6 Study	168
5.3	Number of Sessions Attended by D6 Participants	172
8.1	Intervention Schedule	236

Abbreviations Used in This Thesis

Abbreviation	Phrase
ADA	American Diabetes Association
BCT	Behaviour Change Taxonomy
BECCI	Behaviour Change Counselling Index
BMI	Body Mass Index
CBT	Cognitive Behavioural Therapy
CHD	Coronary Heart Disease
CONSORT	Consolidated Standards Of Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
D6	The Diabetes 6 Study
DESMOND	Diabetes Education for Ongoing and Newly Diagnosed Diabetes
HbA1c	Haemoglobin A1C
HIV	Human Immunodeficiency Virus
ITT	Intention To Treat
MET	Motivational Enhancement Therapy
MI	Motivational Interviewing
MITI	Motivational Interviewing Treatment Integrity
MRC	Medical Research Council
NCM	Nurse Case Managers
NHLBI	National Heart, Lung and Blood Institute
NHS	National Health Service
NICE	National Institute for Clinical Health and Excellence
NIHR	National Institute for Health Research
PCRN	Primary Care Research Network

PCT	Primary Care Trust
PPI	Patient Participation and Involvement
QOF	Quality and Outcomes Framework
QoL	Quality of Life
RCT	Randomised Controlled Trial
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
TIDieR	The Template for Intervention Description and Replication
UKPDS	UK Prospective Diabetes Study
WHO	World Health Organisation

Chapter 1: Context and Aims

Chapter Summary

The randomised controlled trial (RCT) is considered the gold standard method for testing the effectiveness of a new intervention. However, when it comes to evaluating complex interventions, it has its limitations, as the analysis of the treatment effect does not assess the underlying mechanisms that might explain any effect of the intervention. Process evaluation is an umbrella framework for a range of methods for assessing these mechanisms. The concept of process evaluation and the difficulties in defining it and its methods are explored in the context of assessing the effectiveness of a psychological intervention to support self-management in people with type 2 diabetes (T2D).

Introduction

'Science cannot progress without reliable and accurate measurement of what it is you are trying to study. The key is measurement, simple as that.' Robert D. Hare, Professor of Psychopathology and Psychophysiology, University of British Columbia (Spiegel, 2011).

The gold standard method for testing a new intervention is the RCT (Jadad, 1998). An RCT is a comparative study in which participants are allocated randomly to one of two groups, either the intervention (or treatment) or the control (which can be usual care, standard care, a comparison intervention, waiting list or placebo). This ensures that known and unknown confounders that might bias the outcomes are equally distributed between the groups. The intervention and the control group are followed up in parallel over time. The average changes in primary and secondary outcomes are generated and the differences compared using statistical methods. There are many permutations of the RCT such as more than 2 parallel groups, stratification by important confounders, cluster RCTs, and different ways of ensuring unbiased allocation concealment e.g. blinding. Analytical approaches such as intention to treat

(ITT) analysis aim to provide an estimate of treatment effectiveness by ignoring protocol deviations and attrition (Wessely, Slade, & Priebe, 2007).

The RCT is considered the highest quality of evidence to inform clinical practice but it does have limitations. When testing for only one active ingredient against a placebo such as a new cancer drug that targets a specific immunological factor, the biological mechanism to explain the chemical effect has already been hypothesised and is being tested while all other parameters are controlled for. A complex intervention on the other hand is defined as an intervention with multiple interacting components or active ingredients (MRC, 2000). Active ingredients may contribute to the effectiveness of the intervention including contextual or process variables that are not always possible to quantify, and which vary within and between participants, practitioners delivering the intervention, and the organisational and societal context in which the intervention is implemented. Under these conditions, it is more difficult to interpret the meaning of the effect size. Although the quantitative analysis of the primary hypothesis of the RCT can inform whether or not an intervention worked, it is not able to explain how or why it worked. The conventional RCT methods do not typically record or assess these mechanisms or processes and RCTs are therefore limited in their ability to sufficiently analyse the complex interventions made up of multiple components (Ashcroft, 2004; Bensing, 2000; Black, 1996; Feinstein & Horwitz, 1997; Rothwell, 2005; Sanson-Fisher, Bonevski, Green, & D'Este, 2007). A process evaluation provides a solution to this limitation of the RCT of complex interventions.

Process evaluation is an umbrella term that captures a range of contextual constructs and methodologies used to describe the multi-dimensional and multi-factorial mechanisms underlying the effectiveness of a complex intervention. These cannot be understood by the effect size derived from the ITT alone (Oakley, Strange, Bonell, Allen, & Stephenson, 2006). For example, an RCT of a peer education intervention within a gym setting, designed to change sexual behaviours among homosexual men in London was found to have no impact on human immunodeficiency virus (HIV) risk behaviour. The process evaluation found that peer educators had experienced significant communication barriers within the gyms (they found it challenging to engage strangers in conversations about sex) resulting in high rates of attrition, a

finding which not only offered an explanation for the outcome of the trial, but has wider implications for the assumption that recruiting peer educators is a low-cost approach (Elford, Sherr, Bolding, Serle, & Maguire, 2002). Process evaluations may therefore have an explanatory power that enhances the interpretation of the effect size, furthers our understanding of best practice in clinical care and generates new questions.

Background

The decision to fund a proposed intervention via the Medical Research Council (MRC) or National Institute for Health Research (NIHR) will depend on its evidence base and on the needs of the National Health Service (NHS) represented by the National Institute for Clinical Health and Excellence (NICE) (Wanless, 2002) (NICE, 2015). NICE aims to promote clinical excellence in the NHS by developing guidance and recommendations on the most effective treatments and establishing research priorities. The foundation of NICE guidance is the synthesis of evidence from RCTs via systematic reviews, a type of literature review that systematically collates, synthesises and critically analyses multiple research studies using a standardised data extraction method with the ultimate aim of assessing whether the pooled findings offer valid evidence for a given hypothesis or research question (Cochrane Collaboration, 2017). NICE proposed 5 levels of evidence-based medicine, which include: (i) identifying knowledge gaps and formulating a clear clinical question (ii) searching the literature to identify relevant articles (iii) critically appraising articles for quality and usefulness of results; always questioning whether the available evidence is valid, important and applicable to the individual patients (iv) implementing clinically useful findings into practice and (v) evaluating performance using audit (Tidy, 2014).

There is an implicit assumption that implementation of evidence based complex interventions will automatically lead to an improvement in practice (Speller, Wimbush, & Morgan, 2005). However, there is a consistent failure to translate research findings into practice; often RCTs of health promotion interventions that are found to be efficacious fail to be implemented successfully in applied settings

(Glasgow, Lichtenstein, & Marcus, 2003) (Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004) (Clarke, 1995). There are many explanations (i) the intervention may be too costly in the real world of budgets (ii) the results of studies with small or selected samples and tightly controlled interventions may over-estimate the effect (iii) results may not be applicable under different conditions and diverse settings (Glasgow & Emmons, 2007; Glasgow et al., 2004; Schoenwald & Hoagwood, 2001). When we implement an intervention in health services research we are dealing with complex social systems comprising of multiple interactions.

Researchers, and increasingly funders, have called for the inclusion of processes in the evaluation of complex interventions, especially in the field of health promotion (Black, 1996). However, there is a tension between the concept of 'scientific rigour' and the need for more flexible but less well defined research designs (Nutbeam, 1998). There is a need to re-assess the methods used to evaluate interventions, in order to avoid drawing false conclusions from research to the detriment of public health (Speller, Learmonth, & Harrison, 1997).

The field of complex interventions is itself continually growing in complexity as challenges to the population's health evolve. Interventions developing include those that support self management of long term conditions e.g. diabetes, chronic obstructive pulmonary disease (COPD), arthritis and stroke. Where once a public or community health programme focused on changes to physical processes such as development of improved sanitation or educating women about reproductive cycles, now it may involve targeting multiple attitudes and health behaviours related to reducing risk and management of long-term conditions. The nature of complex interventions is multi-faceted and dependent on the social and environmental context in which they are implemented. The MRC guidance for developing and evaluating complex interventions states that they will have a high number of behaviours performed by those delivering and receiving the intervention; will operate on a number of organisational levels; will typically have many outcome measures and a high degree of flexibility or individual tailoring of the intervention will be involved (Craig et al., 2008). For example, interventions to improve the effectiveness of a stroke unit will need to account for multiple interacting variables amongst different healthcare professionals (doctors, nurses, occupational therapists, physiotherapists)

and the wide range of treatments each of these deliver such as prescribing, administering and monitoring medicines, time spent handling the patient and providing emotional support, maximising activities of daily living via aids, and improving function. All of these should have some assessment of competency in delivering each of these active ingredients. Other contextual variables include time allocated to each patient, the extent to which patients receive informal support i.e. from their family and friends, the severity of the stroke and other comorbid conditions.

Studying variation in characteristics between professionals, patients and sites provides an exciting opportunity to maximise RCT findings. While some interventions may be effective in one setting, they may fail in another due to variation in interpersonal, socio-economic, fiscal, demographic, organisational or political factors (Ferlie & Shortell, 2001). Examples of categories of complex intervention include those conducted in the community, for example a community-level HIV prevention programme for young gay men (Kegeles, Hays, & Coates, 1996); those implemented within education systems such as a peer-led sex education intervention at a school (Oakley et al., 2006) and those which utilise psychological methods, such as an intervention employing the methods of motivational interviewing (MI) in order to improve diabetes outcomes in African American adults (Chlebowy et al., 2014).

Interventions that include a psychological element can be particularly complex as they use the alliance, collaboration or relationship between patient and provider as the conduit for changing the patient's psychological state (Craig et al., 2008). There is a need for research methods to be used to decipher the active ingredients of these interventions. These methodologies should be appropriate for the stage of development of an intervention and should make use of both quantitative and qualitative techniques to provide more nuanced understanding of intervention effects. The methods of analysis should be driven by the research question (Mason, 2006). An RCT alone may no longer be sufficient to meet the implementation challenges of modern healthcare research.

One way forward is to use mixed methods which involves, 'collecting, analysing and interpreting quantitative and qualitative data in a single study or in a series of studies

that investigate the same underlying phenomenon' (Leech & Onwuegbuzie, 2009). Adding additional methodologies builds on the RCT's explanatory power (Newman, Ridenour, Newman, & De Marco, 2002). The use of qualitative methods such as interviews or focus groups for example can provide rich qualitative data that may be used to interpret quantitative results. In addition the use of mixed methods can combine empirical precision with descriptive precision (Onwuegbuzie, 2003). Finally, the use of mixed methods allows researchers to gain a more comprehensive picture of the processes at a macro and micro level; it allows us to zoom out by exploring the influence of local policy or other organisational factors, or to zoom in by exploring provider attitudes and beliefs (Onwuegbuzie & Leech, 2005). In turn, quantitative data may complement qualitative data in compensating for the fact that qualitative data cannot be generalised to a wider population. The two sets of methodologies are complementary to one another, in particular because their weaknesses do not overlap. This has been termed the fundamental principle of mixed methods research (Johnson & Turner, 2003). Indeed, a process evaluation of a non-randomised observation or intervention study is more limited than that of a RCT as the former cannot assume an equal distribution of biases.

The Need for Process Evaluation

Process evaluation is a way of opening the 'black box' of research by revealing the mechanisms and processes that are active within it (Baranowski & Stables, 2000; Linnan, 2002; Moore et al., 2015; Oakley et al., 2006; Saunders, Evans, & Joshi, 2005). It is still inadequately understood and the literature describes a poorly demarcated field characterised by a lack of guidelines for the design and conduct of process evaluations, wide variation in terminology used to describe them, varying methodologies and inconsistent or incomplete evaluation attempts (Linnan, 2002). Where process evaluations are reported, there has been a lack of information and depth of reporting, and studies are difficult to replicate (Linnan, 2002). In addition, there has been no consistently used framework for conducting a process evaluation with many researchers using no framework at all and others making their own definitions. While the quality of RCT reporting has gone from strength to strength in the iterations of the Consolidated Standards of Reporting Trials (CONSORT) (Begg

et al., 1996) until recently the importance of improving methodologies for process evaluation has been left behind (Linnan, 2002; Moore et al., 2015).

The Medical Research Council's Guidance for Evaluating Complex Interventions

In 2000 the MRC published a set of guidelines designed to guide researchers in the design and evaluation of complex interventions (MRC, 2000). The guidelines advised on the planning, evaluation and long-term implementation of a new complex intervention using both quantitative and qualitative methods. However, the guidance is based almost entirely on the medical model of clinical trial research and was criticised for its failure to recognise the complexity of different healthcare intervention designs (Mackenzie, O'Donnell, Halliday, Sridharan, & Platt, 2010). A revised version of the guidance was released in 2008, including a recommendation that researchers consider a process evaluation to be a 'good investment'. A great deal of thought was given to a theoretical understanding of the process evaluation. However little practical guidance was provided on how to design and conduct a process evaluation, despite its being considered 'highly valuable' (Craig et al., 2008). The guidance has also been critiqued for excluding practical advice including methodological suggestions at the expense of theory (De Silva et al., 2014).

As process evaluation research developed and its importance became clear, the MRC released 'Process Evaluation of Complex Interventions: UK Medical Research Council Guidance' in 2015 (Moore et al., 2015). However, the guidance remained focused on reviewing previous research in the area and offers little practical advice for researchers wishing to plan and conduct an evaluation. In continually emphasising the complexity and variety of healthcare interventions and the fact that there is no 'one size fits all' approach, the MRC have produced a guide that could be considered vague and difficult to apply to specific research designs. However, the guide is a welcome addition to literature available on process evaluation; we must wait for the discourse as researchers attempt to apply it. The contents of this thesis aim to contribute to this discourse.

A series of ‘events and processes’ have been set in motion to update the guidance, overseen by a scientific advisory group (Skivington, Matthews, Craig, Simpson, & Moore, 2018). However, the update has been subject to delay and is scheduled for publication in 2020.

The Current Problem: Lack of Framework

There is a need for a clear and simple framework for the design and conduct of process evaluations of complex health interventions that can be used alongside an RCT. This would address the problem of inadequate planning and reporting of process evaluations in the same way that the CONSORT checklist was designed to tackle the problem of inadequate reporting of RCTs (Begg et al., 1996). The CONSORT statement comprises a flow diagram (Figure 1.1) and 25-item checklist (Figure 1.2).

Figure 1.1: CONSORT Flow Diagram Reproduced From CONSORT 2010 (Schulz, Altman, & Moher, 2010)

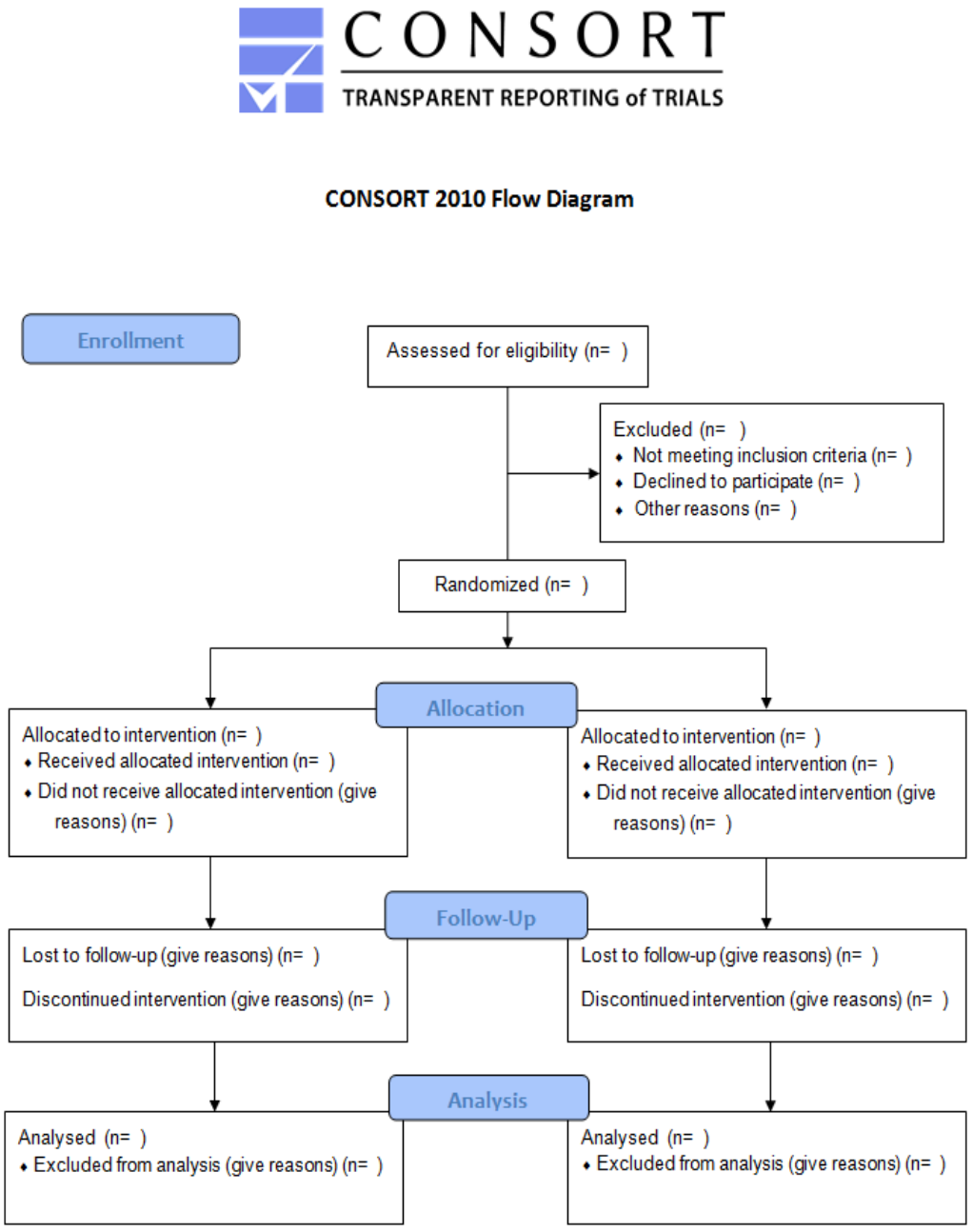


Figure 1.2: CONSORT Checklist reproduced from CONSORT 2010 (Schulz et al., 2010)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

The checklist focuses on how the trial has been designed, analysed and interpreted, while the flow diagram focuses on the flow of participants moving through the RCT. The Template for Intervention Description and Replication (TIDieR) checklist and guidance expanded on item 5 of the 2010 CONSORT statement, with the aim of improving the 'completeness of reporting' (Hoffmann et al., 2014). A similar checklist for process evaluation could aid researchers in the planning and implementation of a process evaluation, defining components and suggesting methodologies. Such a checklist does not exist. At present there is considerable inconsistency in the components of process evaluation studied, the methodologies used to capture data and the reporting of results in the literature. Funding bodies increasingly require more information on the extent of planned process evaluations, yet there is no definition of standard requirements for the methods by which they are conducted and reported in the literature, leading to wide variation and ultimately criticism in peer review.

Many RCTs of complex interventions are therefore conducted without any process evaluation. For example, an RCT set in Massachusetts, US, tested an MI intervention delivered by diabetes educators designed to improve glycaemic control in patients with established T2D and poor control in primary care or secondary care. The intervention did not lead to improved glycaemic control and the authors reported high drop out rates at 6 month follow up (Welch, Zagarins, Feinberg, & Garb, 2011). However, since no process evaluation was implemented it is not possible to produce any further explanations for these negative findings. There were several potential active mechanisms including skill set and competencies of diabetes educators, and baseline diabetes attitudes in the patient group that could have been assessed. There was also no significant change in HbA1c and perhaps the mean baseline value of 73 mmol/mol (equivalent to 8.8%) did not cause sufficient concern to motivate the patient to change. Similarly, an intervention designed to promote physical activity and reduce glycaemic control in patients with poorly controlled T2D was delivered by printed information and telephone counselling methods. The RCT found no significant effect on HbA1c, despite significantly increasing physical activity (Ismail et al., 2010). It is possible that the competencies of telephone counsellors were insufficient since they received only 7 hours training but we do not know, as this was not studied. We also do not know whether they adhered to the intervention as per

protocol. A health coach delivered MI intervention set in China showed significant improvements on psychological variables in poorly controlled T2D patients in both control and intervention groups, but no differential effect on HbA1c at 12 month follow up (Browning et al., 2016). Health coaches were experienced clinicians including doctors, nurses and psychologists but we do not know their individual competencies in delivering the intervention. Interventions were also adapted 'to local context', and we do not know what changes were made. Process evaluations could measure these variables and potentially offer explanations for these findings.

The Setting for This Thesis

The clinical sample in which this thesis is set is The Diabetes 6 Study (D6), which is described in detail in Chapter 5. D6 was a cluster RCT which tested whether practice nurses trained in a package of 6 psychological skillsets could improve glycaemic control in patients with persistently poorly controlled T2D compared to nurses with no psychological skills training. A process evaluation of the D6 study was conducted in parallel with the main RCT and continued after the RCT had finished. The author worked as a Research Assistant for the duration of the study, attending weekly research meetings; taking minutes; filing; data entry and management; searching for missing data; recruiting participants, supporting nurses during their training in D6 psychological skills and collecting qualitative and quantitative data at baseline and follow up. The process evaluation for D6 for reporting to its funders comprised of processes implicit in the main statistical plan for example the 'dose' of the intervention received, plus three additional studies, which were: (i) a quantitative study assessing the fidelity of implementation of the D6; (ii) a qualitative interview study with nurses trained to deliver psychological skills during the D6 study; (iii) a qualitative interview study with patients who took part in the D6 study. The author conducted a scoping study and literature review to develop a framework for process evaluation and applied this to the interpretation of the mechanisms of effect of D6 on glycaemic control.

The Aims of This Thesis

i) To review existing frameworks and methods for conducting process evaluations (Chapter 3)
ii) To apply the findings of this review to develop a theoretical framework for process evaluations of psychological interventions (Chapters 3 and 4)
iii) To test the face validity of the framework on a nurse-led psychological intervention, the D6 cluster RCT, to improve glycaemic control in T2D (Chapters 5-8).

Overview of the Structure of This Thesis

Chapter 2: This describes the epidemiology of T2D, outlining its aetiology, cost, management and the problem of sub-optimal glycaemic control and non-adherence to self-management behaviours. It then describes how psychological therapies may help to promote improved self-management.

Chapter 3: A scoping study provides an overview of the history and evolution of process evaluation theory and the approaches and methodologies that have been used to conduct process evaluations of complex interventions. It will critique the concepts of process evaluation and its methods, before proposing a framework of process evaluation based on this overview.

Chapter 4: The literature on process evaluation of RCTs of psychological interventions designed to improve glycaemic outcomes in T2D will be synthesised. It will summarise the components of process evaluation studied and the methods used. This will give an update of evidence to date of potential mechanisms that may explain the effectiveness or otherwise of psychological interventions in T2D and the research gaps that remain outstanding.

Chapter 5: The protocol and main findings of the D6 study are presented, noting the key issues to consider in the process evaluation. The methods and results for 3 process evaluation components are presented.

Chapter 6: A quantitative study assessing the process evaluation component of fidelity of implementation of the D6 RCT is described, presenting the background, aims, methods, results and discussion.

Chapter 7: A qualitative interview study with D6 nurses is presented, exploring their experiences of participating in the study and their experiences of psychological skills training. It describes the background, aims, methods, results and discussion. This includes the results of 2 process evaluation components.

Chapter 8: A qualitative interview study with D6 patients is described, exploring the range and diversity of their experiences of participating in a test of a new psychological intervention. It describes the background, aims, methods, results and discussion. This includes the results of 2 process evaluation components.

Chapter 9: The final chapter of this thesis is a discussion of the findings including a critique of the strengths and limitations of the process evaluation framework proposed and the studies that were conducted to test it on the D6 study. The results of the process evaluation are discussed within the context of the results of the D6 study and overall conclusions drawn. This will lead to a consideration of the clinical and research implications for the next generation of development in this area.

Chapter 2: Type 2 Diabetes

Chapter Summary

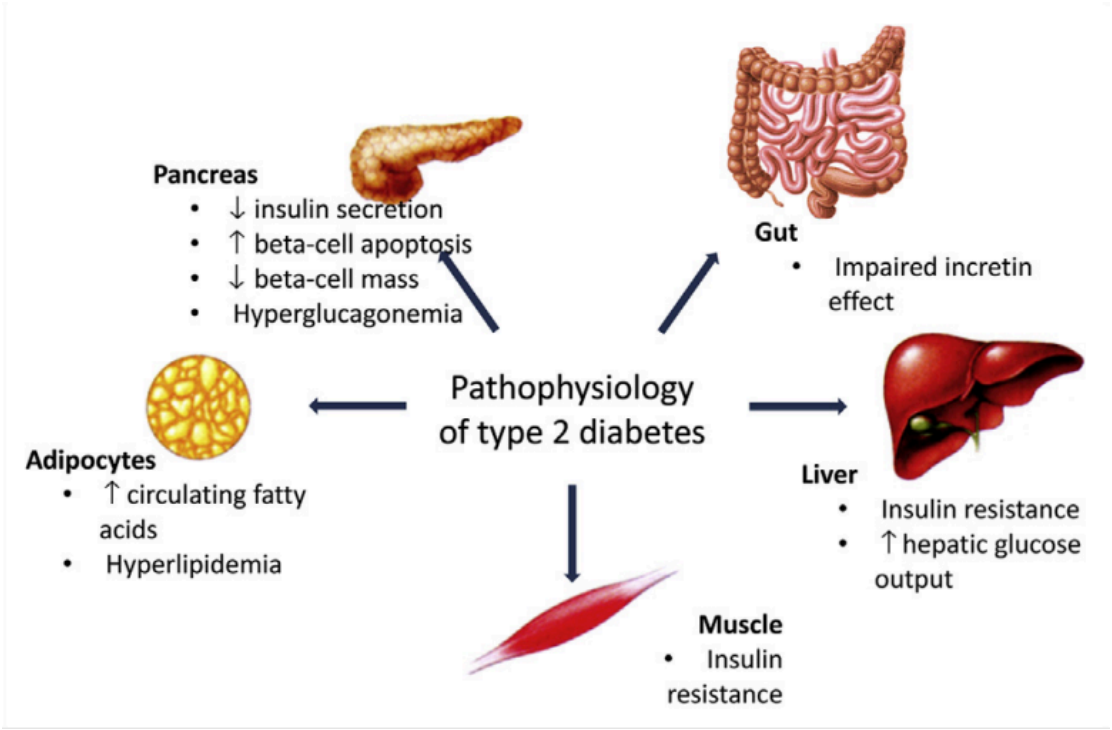
The first chapter outlined the importance of process evaluations of RCTs to improve the quality, interpretation and implementation of the main findings. It briefly introduced the problem of T2D and the rationale for using a complex psychological intervention within primary care to support people with T2D and specifically the setting of the D6 study.

This chapter will expand on the clinical problem of T2D by giving an overview of its epidemiology, aetiology, complications, treatments and cost. The problem of poor adherence to self-care among people with T2D and the growing role of psychological therapies in supporting self-management are discussed.

Overview of Diabetes

Diabetes Mellitus refers to a group of chronic metabolic disorders that are concerned with production and uses of the hormone insulin (American Diabetes Association, 2014). Insulin is the principal anabolic hormone of the body, and is produced in clusters of β cells in the pancreas, called islets. The purpose of insulin is to help transport glucose from the blood stream into the cells of the body, which can then be turned into energy or stored for future use. As glucose is not capable of travelling directly into the cells where it is needed, its levels in the blood rise, signaling the β cells to release insulin. If more glucose is present in the body than is needed, insulin helps to store it in the liver, releasing it in between meals or during exercise. A common description of insulin is that of a key which unlocks cells, allowing glucose to enter and be used for energy via respiration (Pfeifer, Halter, & Porte Jr, 1981).

Figure 2.1: The Pathophysiology of Type 2 Diabetes (Pratley, 2013)



There are two main types of diabetes. Type 1 diabetes (T1D) is to be distinguished as a condition where the β cells have been completely destroyed by an autoimmune reaction, preventing the body from producing any insulin and extraneous insulin given as subcutaneous injections is needed for survival. It accounts for approximately 10% of all cases of diabetes (Atkinson, Eisenbarth, & Michels, 2014). As T1D is not the condition relevant to this thesis, it will not be discussed further.

Type 2 Diabetes

In T2D the beta cells either do not produce enough insulin and/or the cells in the body are resistant to insulin so that it is not used effectively. As a result, glucose accumulates in the blood, leading to hyperglycaemia. Previously known as adult onset diabetes, obesity related diabetes and non insulin dependent diabetes mellitus, T2D usually manifests later in adulthood (peak onset is in the mid 50's in African Caribbean and Asian people and mid 60's in Caucasian people) and accounts for approximately 90% of cases in the UK (DiabetesUK, 2016a).

Insulin resistance or reduced sensitivity is a reduced biological response to insulin. It occurs when the levels of insulin released into the blood are high, over a long period of time. This results in cells becoming resistant to insulin, which in turn results in blood glucose staying in the blood stream stimulating pancreatic β cells to produce more insulin in an attempt to compensate. This further contributes to the elevated insulin level in the blood, exacerbating the problem (Wilcox, 2005).

In the early stages it is possible to reverse the hyperglycaemic state via diet, exercise and lifestyle modification. In recent months there has been media interest in the potential of very low calorie diets to reverse T2D, where the aim is to produce significant weight-loss (Lean et al., 2017). Adjunct therapies may also include medication to increase insulin sensitivity or inhibit glucose production in the liver. As greater demands are made on the pancreas to produce insulin, impairment of insulin secretion worsens as the disease progresses. In other words T2D is a progressive condition, which patients can try to take control of, to reduce or even reverse the rate of progression.

It is possible for people to spend many years in a state of pre-diabetes or impaired glucose tolerance. Pre-diabetes is defined as fasting plasma glucose levels ranging from 6.1-6.9 mmol/l. The World Health Organisation (WHO) states that T2D is diagnosed when symptoms (polyuria or polydipsia plus visual disturbance, unexplained weight loss, recurrent infection, macrovascular complications, retinopathy, nephropathy or neuropathy) are present, plus one of the following (i) a random venous plasma glucose concentration ≥ 11.1 mmol/l or (ii) a fasting plasma glucose concentration ≥ 7.0 mmol/l (whole blood ≥ 6.1 mmol/l) or (iii) two hour plasma glucose concentration ≥ 11.1 mmol/l two hours after 75g anhydrous glucose in an oral glucose tolerance test (WHO, 2011).

Sustained hyperglycaemia is associated with a range of macro- and micro-vascular complications, leading to increased morbidity and premature mortality (WHO, 2016). Hyperglycaemia refers to high blood glucose levels more than 126 mg/dL before a meal and more than 8153 mg/dL after a meal. Symptoms may include increased urination, particularly at night, increased thirst, headaches and tiredness or lethargy.

Complications may be acute or long-term. Acute complications include hyperglycaemia and hyperosmolar hyperglycaemic state, a condition in which high glucose levels can lead to dehydration and potentially serious complications such as coma and death.

Epidemiology of Type 2 Diabetes

In 2014 an estimated 422 million adults were living with diabetes, compared to 108 million in 1980 (WHO, 2016). Diabetes is one of the most common long term conditions in the UK with Diabetes UK estimating that one person every 2 minutes is diagnosed – around 700 people per day and 3.6 million people in total (DiabetesUK, 2016b). It is also estimated that there are around 1.1 million people in the UK who have diabetes but have not yet been diagnosed (DiabetesUK, 2016b). If current trends persist, one in 3 people will be obese by 2034 and one in 10 will develop T2D (DiabetesUK, 2016b).

Complications of Type 2 Diabetes

Macro-vascular Complications

Coronary artery disease: coronary artery disease, also known as ischaemic heart disease, is a disease caused when the coronary arteries become damaged or diseased. The primary cause of this is cholesterol-containing deposits called plaque, which narrow the arteries, reducing blood flow to the heart (Libby & Theroux, 2005).

Peripheral arterial disease: Peripheral arterial disease is a narrowing of arteries that do not supply blood to the heart or brain, most commonly affecting the legs. Symptoms include leg pain when walking which resolves with rest; skin ulcers; bluish skin; cold skin or poor hair and nail growth (Ouriel, 2001).

Cerebrovascular disease: a stroke occurs when blood flow to the brain is restricted. Ischaemic stroke results from insufficient blood flow to the brain, while haemorrhagic stroke is the result of bleeding. A patient with hyperglycaemia is at greater risk of

stroke and this risk is associated with poorer clinical outcomes including higher mortality, especially after ischaemic stroke (Chen, Ovbiagele, & Feng, 2016).

Micro-vascular Complications

Micro-vascular complications refer to the damage of the small vessels of certain organs within the body. Problems manifest themselves in the eyes, kidneys and the peripheral nervous system.

Retinopathy: Diabetic retinopathy is a complication caused by hyperglycaemia damaging the retina and is responsible for >80% of blindness in T2D patients (Lee, Wong, & Sabanayagam, 2015). Diabetic retinopathy is asymptomatic until advanced and patients must therefore be regularly screened using sensitive retinal screening techniques. In the case of regular retinal screening (fundoscopy) problems can be diagnosed and laser photocoagulation applied before retinopathy becomes too advanced. Other eye complications associated with T2D include visual disturbances secondary to osmotic changes, the early development of cataracts and glaucoma.

Diabetic neuropathy: Neuropathy is the most common chronic complication of T2D and relates to a group of nerve disorders. Neuropathy occurs as a result of damage to the small blood vessels that supply the nerves, as a result of high blood glucose. The nerve fibres are damaged or destroyed. Different types of neuropathy include:

i. Sensory neuropathy and the diabetic foot: Sensory neuropathy concerns the nerves, which are responsible for transmitting sensations of touch, pain, temperature and other sensations from the skin, bone and muscles to the brain, and it is estimated that this type of neuropathy may affect up to 26% of people with diabetes (Boulton, 2005). The most acutely monitored sensory neuropathy is in the feet, where minor injuries can be sustained but not noticed by the diabetic person. These injuries, left untreated, may develop into infections or ulcers. Symptoms of sensory neuropathy may include tingling and numbness; loss of ability to feel pain; loss of ability to detect changes in temperature; loss of coordination and burning or shooting pains. The most

serious consequence of these complications is amputation, and diabetes is the most common cause of lower limb amputation in the UK (DiabetesUK, 2016b).

ii. Autonomic neuropathy: Autonomic neuropathy is concerned with nerves that carry signals to the glands and organs. The results of this kind of nerve damage include erectile dysfunction in men, gastro paresis, which can lead to bloating, constipation or diarrhoea, loss of bladder control, irregular heartbeat and problems with sweating (Vinik, Maser, Mitchell, & Freeman, 2003).

iii. Erectile dysfunction: Erectile dysfunction is the most common manifestation of autonomic neuropathy in men, a problem that is exacerbated with age and increased use of antihypertensive medication and also with macrovascular and microvascular disease. Psychological factors also play a role, and may make distinction between physical and psychological causes problematic as well as its presentation, assessment and management (Malavige & Levy, 2009).

iv. Motor neuropathy: Motor neuropathy concerns the nerves that are responsible for movement and can lead to problems with muscle weakness, muscle wasting, muscle twitching and cramping (Vinik, 2016).

v. Nephropathy: Kidney disease (nephropathy) is when the kidney function starts to fail. It is more common in people with diabetes due to damage to the small blood vessels, a process which usually takes at least 20 years (DiabetesUK, 2016a). Approximately 3 out of 4 people with diabetes will develop some stage of kidney disease during their lifetime and kidney disease accounts for 11% of deaths in T2D (UK, 2016). It is the most common cause of dialysis and the epidemic of T2D has seen the demand on dialysis units increase, representing one of the most expensive complications (Williams, Van Gaal, & Lucioni, 2002).

Risk Factors

The risk of developing T2D is cumulatively determined by a combination of genetic and metabolic factors within a particular environment. Genetics and family history combine with increasing age, being overweight or obese, being physically inactive and/or having a poor diet to elevate risk. The worldwide epidemic of T2D is rising in parallel with the epidemic of obesity (Gan, 2003).

Excess body fat as a result of overweight and obesity is considered the strongest overall risk factor, and obesity is estimated to attribute up to 50% of the global disease burden. This body fat percentage may be increased by poor dietary behaviours, such as high glucose consumption and/or high fat intake and/or reduced physical activity. This leads to higher waist circumference and BMI, which is associated with increased risk of T2D, although this risk varies among different ethnicity populations (Misra, Wasir, & Vikram, 2005).

Other factors identified as indicating a higher than average risk of developing T2D include having specific endocrinopathies (e.g. Cushing's Syndrome), receiving treatment with diabetogenic drugs (e.g. high dose glucocorticoids), having had gestational diabetes, and cigarette smoking (WHO, 2006).

People may spend many years in a state of pre-diabetes when blood glucose levels are higher than normal but do not meet diagnostic criteria. One in 3 adults are estimated to have prediabetes in England and therefore have a high risk of developing T2D (Mainous, Tanner, Baker, Zayas, & Harle, 2014).

Economic Cost of Diabetes

Diabetes represents a great economic burden, with 10% of NHS budget (£10 billion per year) spent on diabetes care – £1 million an hour. The combined direct and indirect costs associated with UK diabetes care total £23.7 billion, and this is expected to rise to £39.8 billion by 2035 (DiabetesUK, 2016a).

People with diabetes are twice as likely to be admitted to hospital, and net ingredient prescription costs across primary care in the UK in 2014/5 totaled £803 million. Diabetes also contributes 44% of combined angina, myocardial infarction, heart failure and stroke hospital bed days (DiabetesUK, 2016a). Diabetes is the most common cause of lower limb amputations, renal dialysis and blindness (Hinchliffe, Jeffcoate, & Game, 2006).

In the financial year 2015/16 there were 49.7 million items prescribed for diabetes at a total net ingredient cost of almost £100, 000 to the NHS. The number of items prescribed for drugs used in diabetes was 49.7 million (Digital), 2016).

Management of Type 2 Diabetes

The evidence base for management of T2D is constantly evolving and is a dynamic field. NICE summarises the evidence base and regularly updates its guidance (NICE, 2015).

Self-management: T2D is a progressive condition that requires intensive daily management, and there is an increasing expectation among both health professionals and patients that a significant part of this responsibility of care rests with the patient. The skills required to effectively manage T2D are multiple and include the performance of lifestyle behaviours such as adhering to a healthy diet plan and exercise regime, administering medication including insulin injections, multiple medications (including those to control glucose, blood pressure, cholesterol and weight (King, Peacock, & Donnelly, 1999)) and self-monitoring of blood glucose levels. A large degree of knowledge is necessary, in combination with self-motivation and an appropriate cognitive skills set, such as planning, comprehension and memory. However, knowledge and structured education alone do not ensure optimal self-management and improvements in glycaemic control (Deakin, 2011).

Non-Pharmacological Treatments

Patient education: Support for people with T2D begins with referral to a patient education program such as Diabetes Education for Ongoing and Newly Diagnosed Diabetes DESMOND (Davies et al., 2008), X-PERT (Deakin, Cade, Williams, & Greenwood, 2006) and the Diabetes Manual (Sturt et al., 2008). Referral to a program is recognised as an essential component of NHS diabetes healthcare (NICE, 2011). The aim of such programs is to address patients' individual health beliefs and support behaviour change to optimise blood glucose control, cardiovascular risk factors, depression and quality of life. While evidence for the effect of these programs on clinical outcomes has mainly been inconclusive (Deakin et al., 2006; Khunti et al., 2012), a systematic review concluded that small benefits were generally long-lasting (Loveman, Frampton, & Clegg, 2008) and the majority of patients find them beneficial in terms of acceptance of diagnosis (Ockleford, Shaw, Willars, & Dixon-Woods, 2008) and increasing diabetes knowledge (Deakin, 2011). Uptake of referrals to structured diabetes education, however, is consistently poor (Winkley et al., 2015; Winkley et al., 2016).

Lifestyle interventions: Lifestyle intervention is a crucial aspect of T2D self-management, particularly the maintenance of a healthy diet and physical activity levels and there is an urgent need for interventions that produce sustained effects (Glasgow, Vogt, & Boles, 1999).

Diet: Dietary management is a crucial aspect of T2D management. People with T2D are advised to follow a 'normal' balanced diet, which is rich in complex high fibre carbohydrates and low in saturated fats and cholesterol. Meals should be taken at regular intervals and an effort made to balance calorific intake in order to maintain normal body weight. It is recommended that 'diabetic speciality foods' are avoided, since they typically contain fructose or sorbitol which can lead to side effects such as diarrhoea. A landmark study published in The Lancet in 2017 reported the results of the DiRECT study, a cluster-randomised RCT which assessed whether an intensive weight management program implemented in a primary care setting could achieve remission of T2D. Among the sample of 306 patients at 49 primary care practices in

Scotland remission was achieved in 46% of intervention group patients at 12 month follow up (Lean et al., 2017).

Physical exercise: Regular physical activity is recommended for people with T2D as it may have beneficial effects on metabolic risk factors for the development of T2D complications (Castaneda et al., 2002). Obesity is associated with insulin resistance, hyperinsulinemia, dyslipidemia and hypertension (DesprÉs, 1997). A meta-analysis synthesising data from RCTs which tested the effects of exercise on glycaemic control and body mass in T2D found that exercise decreased HbA1c sufficiently to decrease the risk of diabetic complications (Boulé, Haddad, Kenny, Wells, & Sigal, 2001).

Pharmacological Treatments

Oral Hypoglycaemic Agents

Biguanides: The only biguanide used in the UK is metformin, usually the first medication prescribed if dietary modification and physical activity adjustment have not been successful in reducing blood sugar levels (Rojas & Gomes, 2013). The exact mechanism of metformin is not understood, but it decreases hepatic glucose production and increases sensitivity to insulin (i.e. targets insulin resistance). It does not cause weight gain or hypoglycaemia and in obese patients is associated with a significant reduction in diabetes related events, mortality and stroke (King et al., 1999).

Sulphonylureas: The action of sulphonylurea is by stimulating pancreatic insulin production (Melander, Bitzén, Faber, & Groop, 1989). Examples include gliclazide and glimeprimide. In contrast to metformin, sulphonylureas may induce hypoglycaemia as a result of excess insulin production and release. They may also induce weight gain, abdominal upset, headaches and hypersensitivity reactions (Zimmerman, 1997).

Alpha glucosidase inhibitor: Also known as acarbose, this delays the absorption of carbohydrates in the intestine, consequently lowering postprandial blood glucose levels. This is only effective in patients with adequate β cell function, and the drug commonly produces gastrointestinal side effects (Laube, 2002).

Prandial glucose regulators: These work in a similar way to sulphonylureas in that they stimulate the cells in the pancreas to produce insulin. They have a faster action, but a shorter duration of therapeutic effect and so must be taken half an hour prior to meals and if a meal is missed, the dose is not taken (Owens, 1998). Examples include repaglinide.

Thiazolidinediones: This group of medicines is known as insulin sensitisers or glitazones, reducing insulin resistance and improving sensitivity allowing the insulin that is produced by the body (or exogenous insulin injection) to be used more effectively. A secondary action is protection of pancreatic cells, allowing them to produce insulin for an extended period of time. Side effects include weight gain and fluid retention. Thiazolidinediones can be used as a monotherapy or added to metformin or sulphonylureas (Schoonjans & Auwerx, 2000).

Incretin Mimetics: Incretin mimetics work by increasing levels of natural gut hormones called incretins, which help the body to produce more insulin only when it is required i.e. after meals, and reduce the amount of glucose produced by the liver when it's not required. They can also reduce appetite, and the rate at which the stomach digests food. Examples include exenatide and liraglutide (Nielsen, 2005).

DPP-4 Inhibitors (gliptins): DPP-4 (dipeptidyl peptidase-4) inhibitors block the action of DPP-4, a natural gut hormone that is an incretin antagonist. They are usually prescribed for patients who have not responded well to drugs such as metformin and sulphonylureas. Examples include sitagliptin and saxagliptin (Scheen, 2010).

SGLT2 Inhibitors: SGLT2 inhibitors works in two ways: i) by reducing the amount of glucose re-absorbed at the kidney tubule (it is passed in the urine) and ii) reducing the amount of glucose in the blood. Examples include dapagliflozin and empagliflozin (Taylor, Blau, & Rother, 2015).

Insulin

People with T2D may be advised to begin insulin therapy when blood glucose levels cannot be adequately controlled with the use of metformin plus one other oral anti-diabetic drug; or if that person is hyperglycaemic and would prefer to start insulin rather than add another anti-diabetic drug. Insulin may also be used when anti-diabetic drugs cannot be tolerated or are contraindicated (NICE, 2015).

Reasons that insulin may not be recommended include i) obesity, since insulin use may lead to weight gain, ii) risk of hypoglycaemia (when the person's risk may outweigh the potential benefit of taking insulin) iii) needle phobia or anxiety, iv) personal choice or v) concerns relating to a license to drive certain vehicles (NICE, 2015).

There are 3 main types of insulin including animal, human (synthesised to match human insulin) and analogue (insulin replicas). Most people use human or analogue insulin, although animal insulin is used in some cases. Insulin is then further categorised according to the speed at which it works. Rapid acting insulin is usually taken just before a meal, acting very fast to minimise the rise in blood sugar that follows a meal. Short acting insulin is also usually taken before a meal, although is not as fast to act. Rapid and short-acting insulin are often referred to as 'bolus' injections. Intermediate acting insulins are also known as isophane insulins and are often taken in conjunction with short acting insulin. They begin to take effect within the first hour of injecting and are followed by a period of peak activity, which can last for 7 hours, followed by a tailing off period. Long acting insulins can last for up to 24 hours and ensure a consistent delivery throughout the day. Intermediate and long-acting insulins are known as 'basal' or background insulins. Usually in T2D management people who need insulin start with one injection of basal insulin at night-time and may then progress to a basal bolus insulin regimen if glycaemic control does not improve sufficiently and which can occur in the context of T2D progression and reduced insulin secretion.

The Clinical Problem of Persistent Suboptimal Glycaemic Control

Despite available treatments, a high proportion of patients with T2D remain poorly controlled (good blood glucose control is defined as 42-53 mmol/mol (equivalent to 6-7%), moderate control as 63-74 mmol/mol (equivalent to 7.9-8.9%) and poor control as 85-107 mmol/mol (equivalent to 9.9-11.9%) (WHO, 2011). Patients struggle to balance the demands of self-management, medication adherence and lifestyle modification (Murphy et al., 2017).

Causes of poor glycaemic control among T2D patients specifically include lack of diabetes knowledge; poor adherence to lifestyle recommendations; poor adherence to insulin or other medication; insulin refusal; side effects; infrequent attendance of routine appointments; denial that diabetes is a problem; mental health problems and social factors, for example family problems (Khan, Lasker, & Chowdhury, 2011; Khattab, Khader, Al-Khawaldeh, & Ajlouni, 2010).

Psychological Problems and Glycaemic Control

Patients with T2D have many psychological problems, which contribute to sub-optimal glycaemic control. Psychological barriers to adherence include depression, anxiety, disordered eating, unhelpful health beliefs, stigma, and diabetes specific fears (Ismail, Winkley, & Rabe-Hesketh; Kenardy et al., 2001; Lustman et al., 2000).

The most common mental health problem in people with T2D is depression, with rates increased at least 2-fold when compared to the general population, and prevalence rates at around 26% (Anderson, Freedland, Clouse, & Lustman, 2001). Depression is associated with adverse outcomes in diabetes and is associated, however it is measured (by clinical criteria or depression screening measures), with a 2-5 fold increased risk of mortality (Black, Markides, & Ray, 2003; Ismail, Winkley K Fau - Rabe-Hesketh, & Rabe-Hesketh, 2004; Katon et al., 2005).

Cross-sectional studies suggest that depression is associated with sub-optimal glycaemic control (Ciechanowski, Katon, & Russo, 2000a; Clark, Hampson, Avery, & Simpson, 2004) and some but not all observational studies support these findings

(Das-Munshi et al., 2007; Ismail et al., 2004; Katon et al., 2005; Nakahara et al., 2006). Furthermore, sub-clinical depression and dysthymia may also have prognostic significance, since the effect of depression on mortality in those with diabetic foot ulcers has been found to be similar regardless of whether depression is mild, moderate or severe (Das-Munshi et al., 2007; Lustman, Griffith, Freedland, & Clouse, 1997).

Anxiety is also more common in people with T2D (Grigsby, Anderson, Freedland, Clouse, & Lustman, 2002) and a systematic review of 18 studies to determine the level of generalised anxiety disorder in diabetes estimated the prevalence at 14% (2-3 times that of general population), and sub-threshold anxiety at around 27% (Grigsby et al., 2002). At present, it remains to be established whether anxiety disorders are comorbid with depression or whether they are related to specific self-care activities, for example injecting insulin or fear of hypoglycaemia.

Disordered eating, particularly night eating behaviours, is thought to be more common in people with T2D (Allison et al., 2007). Its significance may be that it contributes to progressive hyperglycaemia, and may be a response to fears of hypoglycaemia developing during the night (Allison et al., 2007). In addition, binge eating disorder may be more prevalent among the T2D population, with a recent systematic review and meta-analysis reporting rates of 6.9% (Cheah, 2008). It is associated with a BMI and increased psychological distress (Herpertz et al., 2000; Kenardy et al., 2001).

Unhelpful health beliefs have been associated with maladaptive coping behaviours in patients with T2D (Searle, Norman, Thompson, & Vedhara, 2007). According to the Common Sense Model of Illness Representations, patients' beliefs about their condition fall into 5 categories as follows (i) Identity, including beliefs about symptoms (ii) Timeline, including beliefs about the course and duration of the illness (iii) Consequences, or beliefs about the effects of the illness (iv) Cause, including beliefs about perceived cause and (v) Cure/Control, or beliefs about potential recovery from the illness or potential to control it (Leventhal, Brissette, & Leventhal, 2003). Beliefs about diabetes medications have also predicted poor medication adherence, including 'believing there is no need to take medicines when blood glucose is normal', 'worrying about side effects of diabetes medicines' and 'feeling

medicines are hard to take.' These beliefs are potentially modifiable and are logical targets for educational programmes (Mann, Ponieman, Leventhal, & Halm, 2009).

Social stigma is also a problem for people living with T2D. Qualitative research has shown that patients are subject to negative stereotyping, discrimination and restricted opportunities (for example in their career) (Browne, Ventura, Mosely, & Speight, 2013). There is significant social stigma surrounding the public injection of insulin, with patients reporting 'contempt' from strangers as a result of the perception that they are 'intravenous drug addicts' or 'self inflicting the disease as a result of over-indulgence with food.' Patients may therefore avoid injecting insulin in public, representing a barrier to self-management (Tak-Ying Shiu, Kwan, & Wong, 2003). Stigmatisation from healthcare providers can also be a problem, with a systematic review concluding that negative attitudes towards obesity can negatively impact patients' self-management (Teixeira & Budd, 2010). Shame and stigma of diabetes (e.g. not wishing to tell others of diabetes diagnosis) is also a barrier to attendance at structured diabetes education programmes (Winkley et al., 2015).

Diabetes-specific worries can also represent barriers to self-care in T2D and may include difficulties in accepting and adjusting to the diagnosis; worries and fears about complications; self-testing and injecting; hypoglycaemia; acceptance of insulin therapy and concerns about body image and eating (Peyrot et al., 2005a) (Snoek, Bremmer, & Hermanns, 2015). For example, one qualitative study conducted in primary care practices in Kuala Lumpur found that patients' resistance to insulin treatment was due to fears around self-injection; needle phobia; injection pain; embarrassment; social stigma; a belief that insulin can cause organ damage; a belief that their diabetes was not serious enough or a belief that insulin was 'for more serious disease only' (Hassan et al., 2013). Another qualitative study conducted in Singapore found that patients perceived insulin as punishment for failure with their current regimen and some refused to acknowledge the need for insulin therapy (Tan et al., 2011). Levels of diabetes-distress are higher in primary care patients with T2D compared with secondary care in The Netherlands (4 versus 19% respectively) (Stoop et al., 2014) and higher in patients from ethnic minority backgrounds (Stoop et al., 2014) (Strandberg, Graue, Wentzel-Larsen, Peyrot, & Rokne, 2014). Furthermore,

measures of diabetes distress have shown moderate to strong correlations with self-report measures of depression in a sample of 463 T2D patients in the USA (Fisher, Glasgow, & Strycker, 2010), 184 patients with T1D (n=51) and T2D (n=133) in Australia (Reddy, Wilhelm, & Campbell, 2013) and in 627 outpatients with T1D (n=280) and T2D (n=347) in The Netherlands (Van Bastelaar et al., 2010). Some studies suggest that the link between glycaemic control and diabetes distress is stronger than the link between glycaemic control and depression in T2D (Reddy et al., 2013) (Fisher et al., 2007) and some studies show that diabetes distress mediates the relationship between depression and glycaemic control (Van Bastelaar et al., 2010) (Schmitt et al., 2015).

Can Psychological Therapies Improve Outcome in Type 2 Diabetes?

Psychological problems are associated with poor glycaemic control in T2D, for example, problems such as depressive disorders (De Groot, Anderson, Freedland, Clouse, & Lustman, 2001; Lustman et al., 1997) and disordered eating (Kenardy et al., 2001) and are associated with diabetes complications (De Groot et al., 2001) and poor glycaemic control (Lustman et al., 1997). In a systematic review and meta-analysis of RCTs of psychological interventions to improve glycaemic control in patients with T2D, psychological interventions were associated with improvements in long-term glycaemic control and levels of psychological distress (Ismail et al.).

Psychological approaches may be beneficial in improving adherence to diabetes self care behaviours and consequently glycaemic control, particularly if integrated into usual diabetes care. Talking therapies, during which the patient and therapist work collaboratively to address barriers to self-care and unhelpful health beliefs, may be beneficial. The most commonly advocated talking therapies are MI and CBT.

A systematic review of psychological therapies designed to improve outcome in T2D found a reduction of ~8 mmol/mol in glycated haemoglobin in those receiving psychological therapy, close to the minimum clinical significance. Psychological strategies used ranged from behavioural techniques such as stress management and relaxation therapy (Surwit et al., 2002) to cognitive strategies designed to target

depressive symptoms (Lustman, Griffith, Freedland, Kissel, & Clouse, 1998). However, it should be noted that the validity of the findings were limited due to methodological limitations of the studies selected for inclusion. An update to the review 4 years later found little improvement in the quality of studies and a slightly reduced effect size (Alam, Sturt, Lall, & Winkley, 2009). This is discussed further within the context of the literature review described in Chapter 4.

Psychological therapies can be beneficial when delivered by experts but this is not a practical or affordable solution for the NHS. Experts in psychological therapies are costly and their expertise is possibly best reserved for a small group of highly complex patients with multiple morbidities (Nicholson, Taylor, Gosden, Trigwell, & Ismail, 2009). At present there remains a large sub group of people with T2D and sub-optimal glycaemic control that would benefit from receiving lower intensity psychological support in primary care and it may be that existing nursing staff can be trained to deliver this effectively.

One systematic review found no difference in the reduction in HbA1c in those interventions delivered by 'generalists' i.e. doctors and nurses with no mental health training (pooled mean reduction 0.51% 5 mmol/mol (95% CI: -0.50 to 0.04: 9 RCTs with a sample size of compared to mental health workers such as psychologists and psychotherapists (0.57% or 6 mmol/mol (-0.36; 95% CI: -0.61 to 0.12: 9 RCTs with a n=832) sample size of n=561) (Alam et al., 2009). They concluded that training generalist clinicians in psychological therapies could represent a viable pathway to improved outcome in subgroups of T2D patients with suboptimal glycaemic control.

Primary care practice nurses have been successfully trained to deliver CBT for other conditions with some success. For example, an RCT of CBT versus usual care for adults with persistent insomnia found that CBT delivered by primary care nurses was associated with significant improvements in self-reported sleep latency, wakefulness after sleep onset and sleep efficiency and that these improvements were partly sustained at follow up (Espie et al., 2007). An RCT of primary care nurse-delivered CBT as an adjunct to pharmacological therapy showed significant improvements in outcome for patients with irritable bowel syndrome up to 6 months after treatment (Kennedy et al., 2005) and studies have shown that primary care nurses find training

in psychological therapies such as MI to be a valuable tool for health promotion practice (Brobeck, Bergh, Odencrants, & Hildingh, 2011).

Training primary care staff such as practice nurses may therefore represent a cost-effective solution to the clinical problem of the T2D patient in primary care who struggles to achieve optimum glycaemic control as a result of psychological barriers to self-care. A recent RCT of collaborative care delivered by practice nurses for people with depression and T2D and/or cardiovascular disease found that problem solving therapy targeted at improving depressive symptoms integrated into regular diabetes care was associated with an improvement on all outcomes (Aiken, Clarke, Sloane, Sochalski, & Silber, 2002). A much larger sub-group of T2D patients however have sub-clinical depressive symptoms and diabetes related distress, and they could potentially benefit from practice nurses trained in psychological therapies, something which has not been adequately studied (Aikens, Kiolbasa, & Sobel, 1997; Charman, 2000).

Summary and Conclusions

T2D is a global problem that is accelerating in parallel with the global obesity epidemic. A condition requiring significant self-management on the part of the patient, it demands multiple skills including administration of polypharmacy, blood glucose monitoring and adherence to diet and exercise regimes. There are many psychological barriers to self-management, which must be addressed if self-management among those with persistently sub-optimal glycaemic control is to improve. However, experts in psychological therapies are a scarce and costly resource for the NHS. If existing staff can be trained to deliver psychological therapies to this group of patients, for example in primary care, this may represent a cost effective solution.

Chapter 3: The Process Evaluation of Complex Interventions

Chapter Summary

The preceding chapter emphasised the scale of the burden of T2D and the psychological difficulties that can interfere with self-management. The evidence for the effectiveness of psychological therapies in supporting self-management and improving glycaemic control remains unclear.

This chapter will expand the different types of complex interventions, describe the different definitions for process evaluation and its importance in the evaluation of the RCT. A scoping study of the evolution of process evaluations was conducted which showed the various efforts that researchers have made to define them and develop frameworks and methods used to conduct process evaluations. Synthesising the different approaches, a framework for process evaluation of psychological interventions is proposed for preliminary application.

Definition of a Complex Intervention

A complex intervention is a treatment with multiple interacting components (MRC, 2000).

The MRC states that there are a number of characteristics of complexity, as defined by their guidance for developing and evaluating complex interventions (Craig et al., 2008; Moore et al., 2015; MRC, 2000). These characteristics are:

(i) Number of and interactions between intervention components (in both control and experimental conditions)
(ii) Number and difficulty of behaviours required by those delivering or receiving the intervention
(iii) Number of groups or organisational levels that the intervention is targeting

(iv) Number and variability of outcome measures
(v) Degree of flexibility or tailoring of the intervention permitted.

Complex interventions are widely used in health service, education and social policy research and typically present several challenges to researchers as follows:

(i) Problems standardising research design and methodology because of multiple variations and interactions between different components
(ii) Variations in the context to which they are applied
(iii) Use of appropriate statistical and qualitative methods because the potential active ingredient is not clearly defined at the outset.

Examples of complex interventions in different contexts include:

(i) A trial in the service delivery and **organisation context**, such as one to assess the benefits of a specialised hospital pain unit involving complex interdisciplinary communication and collaboration, resulting in clinical and administrative challenges (Courtenay & Carey, 2008)
(ii) Interventions designed to assess the behaviour of **public health** professionals, such as an intervention testing a new method of digital treatment decision support. Interventions involve training and implementation components and barriers such as clinicians' resistance to change (Kaushal, Shojania, & Bates, 2003)
(iii) Community interventions such as **health education** programs targeted at people at risk of developing long-term health conditions where fidelity may be difficult to measure (Breitenstein et al., 2010)
(iv) Group **psychological interventions** such as a meditation group designed to reduce anxiety among people with cancer which involves the challenges of developing a therapeutic alliance in a group setting and participant and therapist barriers to participation (Carlson, Ursuliak, Goodey, Angen, & Speca, 2001)
(v) Individual **psychological interventions** such as CBT for people with depression, which rely on the therapeutic alliance between patient and therapist and may be affected by both parties' preconceptions regarding psychological therapies (Krupnick et al., 1996).

The type of complex intervention relevant to this thesis is the psychological intervention. Therefore, the term psychological intervention will replace complex intervention from this point forward.

What is Process Evaluation?

Process evaluation is an umbrella term for a range of methods for evaluating psychological interventions. Process evaluations may be conducted before, during or after the RCT to understand underlying mechanisms or processes that explain how and why the intervention is or is not effective in improving the intended outcome.

The MRC defines process evaluation as, 'a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors. Process evaluation is complementary to, but not a substitute for, high quality outcomes evaluation' (Moore G, 2014).

Process evaluations aim to identify which components and mechanisms are the active ingredients contributing to efficacy (Oakley et al., 2006). They may employ a range of methodologies to identify these active ingredients, and they can measure multiple contextual variables and processes, which may vary between and within study participants, interventionists and sites to mediate outcome. The greater the number of potential active ingredients in a psychological intervention, the greater the variation in the overall conduct of the study and the interpretation of results. It is in this context that process evaluation becomes more relevant for interpreting quantitative findings and translating into practice.

The basic principles of process evaluation are (Oakley et al., 2006):

(i) The theoretical tenets underpinning an intervention and how they relate to intervention components
(ii) The implementation of the intervention, including the quality and quantity of what was delivered
(iii) The context in which the intervention was delivered

(iii) The mechanisms of impact of the intervention

(iv) How an intervention can be implemented in a given context.

These processes can occur at a number of different levels within the intervention, including:

(i) The patient or participant level

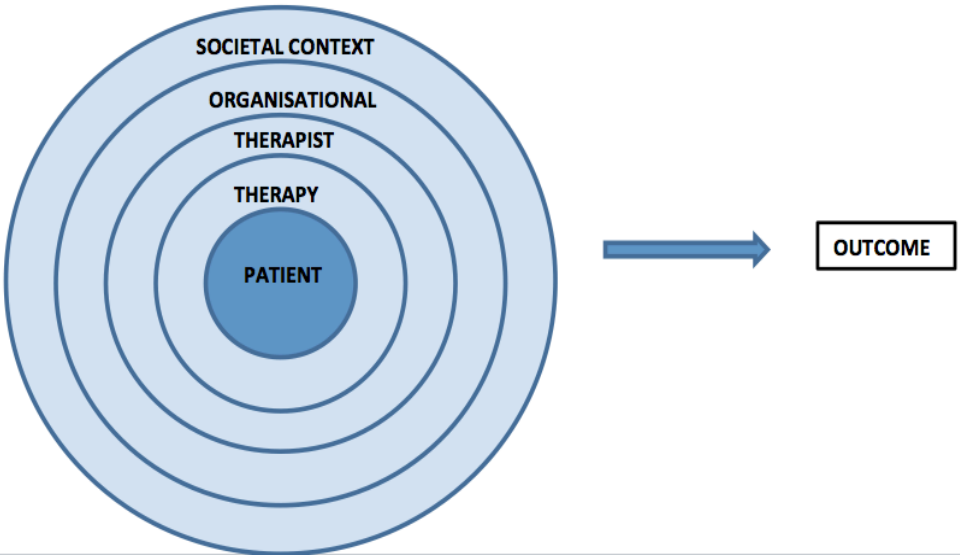
(ii) The therapy or program level or content

(iii) The therapist or interventionist level

(iv) The organisational level

(v) The societal context.

Figure 3.1: Levels of a Complex Intervention at Which Measurable Processes Occur



Despite a general consensus of the basic principles, at the time of writing this thesis, there is is no clear consensus as to the most suitable framework for conducting process evaluation. While the field of quantitative methods has exploded (for example there are now 14 variations on the CONSORT statement), that of process evaluation has been somewhat slower. A well-defined framework for process evaluation will enable researchers facing an already huge analytical task to make the most efficient, parsimonious use of resources by selecting the most appropriate processes from the framework for study.

Formative and Summative Process Evaluation

Process evaluations may have both formative and summative purpose. Formative process evaluation ensures a programme is feasible, appropriate and acceptable (Saunders et al., 2005). The difference between formative and summative evaluation was first defined in the 1960's by Scriven (Tyler, Gagné, & Scriven, 1967) who identified the purpose of formative evaluation as being 'to collect information that can be used primarily for ongoing program development and improvement' and the purpose of summative evaluation as being, 'to make an overall judgment about the effectiveness of the program.' Formative evaluation has been historically under-researched in comparison to summative (Dehar, Casswell, & Duignan, 1993) although in recent years this has begun to change (Berkowitz et al., 2008; Braden, 1992; Evans, Scourfield, & Murphy, 2015).

Formative evaluation uses methods such as systematic review to assess evidence base, consultations with programme developers and stakeholders to elicit knowledge, assumptions and understandings of intervention theory, and interviews with target populations to understand contextual influences and ascertain feasibility and acceptability of the intervention (Evans et al., 2015; Evans, Raines, & Owen, 1989). The MRC process evaluation framework recommends a feasibility and piloting stage take place after development of an intervention in order to assess feasibility and optimise design (Moore et al., 2015).

Formative evaluation is important because it represents an opportunity to make adjustments to a programme at a point when its components are not well established. Hornik argued that by the time a programme reaches the point of outcome evaluation, too many irreversible commitments have been made (Hornik, 1980). However, Evans et al suggested a more ongoing role for formative evaluation of data in their definition, which states that formative evaluation is, 'integrated into the development and implementation of a research project. It provides assessment information within a feedback loop. This assessment identifies the strengths and weaknesses of the project as it progresses. Data obtained from evaluations may be used to modify and redevelop the measurement instruments, the research design and the intervention program

during the course of implementing a project' (Evans et al., 1989). McClintock later broadened the definition, framing the researcher as not just methodologist but agent of change, defining formative evaluation as, 'the systematic use of empirical procedures for appraisal and analysis of programs as a way of providing ongoing information to influence decision making and action on policy, resource allocation, and program operations' (Fitzpatrick, 1988; McClintock, 1984). Later definitions consolidated the focus on the potential of a formative evaluation to keep a programme on track (Helitzer et al., 1999; Israel et al., 1995; McGraw et al., 1994).

Examples of formative evaluation programmes include the formative stage of The Stanford Five-City Program, which tested whether a community-wide health education in 2 cities can reduce coronary artery disease and stroke over a 64 month follow up period (Farquhar et al., 1990). Intervention groups received a health education intervention based on a communication-behaviour change model and social learning theory (Bandura, 2011). Pilot investigations conducted by the authors as part of a formative evaluation focused on the health communication campaign programmes and project materials. The formative analysis enabled the authors to better define study objectives, define target audience and identify intended intervention effects. The second phase of formative research was termed 'concept testing' and involved an investigation of the clarity of the intervention purpose measured by 'tracking' whether the programme materials had reached the audience as intended (Farquhar et al., 1985).

Recently, researchers have argued that formative process evaluation must become more pragmatic (Evans et al., 2015). Pragmatic formative evaluation refers to formative evaluations of interventions that are likely to be already used in routine practice but have not yet been subjected to rigorous theoretical assessment. Pragmatic formative evaluations can therefore provide an evidence base for widely practiced interventions about which a number of assumptions have been made, while also providing the opportunity to conduct a formative evaluation in a real world setting. For example, a pragmatic formative process evaluation of a school based social and emotional learning intervention, recommended as best practice in Welsh schools for managing challenging behaviour found multiple iatrogenic effects as a result of stigmatising targeting practices. Qualitative interviews with 4 students taking part in

the study identified stigmatising practices around themes including negative labeling of children, leading to both stigma and exclusion of the child; a 'badge of honour' effect among peers; and amplified deviancy as result of intervention group composition. In this case, pragmatic formative evaluation successfully identified that intervention methodology was not supportive of processes and outcomes (Evans et al., 2015).

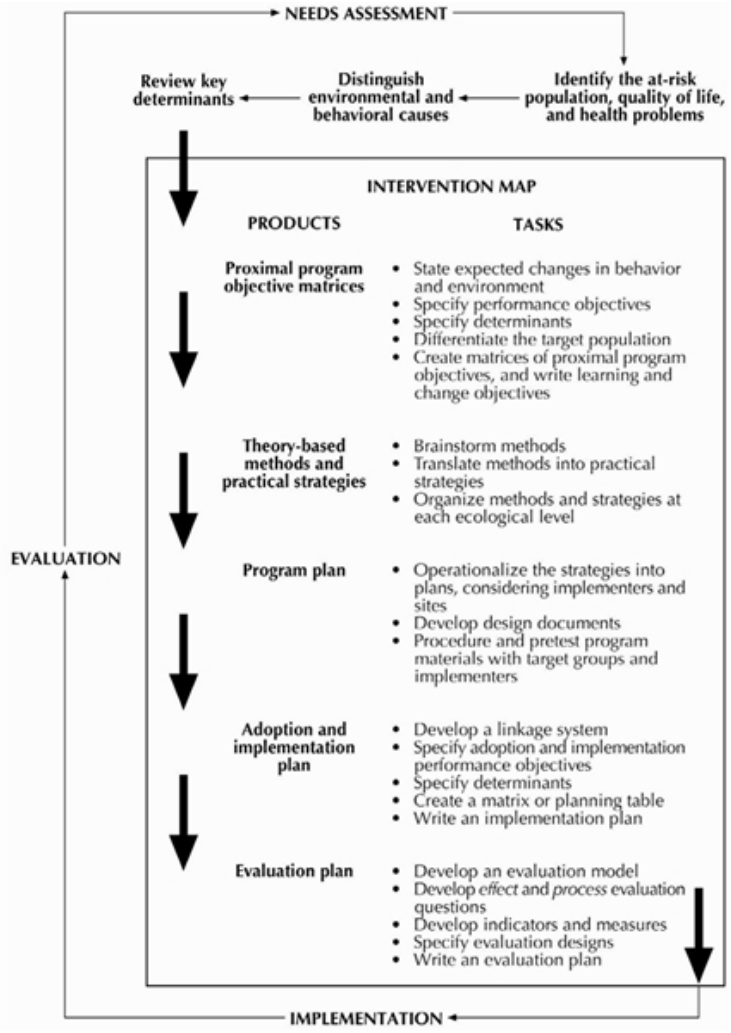
Summative evaluation refers to overall judgements made about the efficacy of an intervention (Tyler et al., 1967). Although an intervention may have been evaluated at the formative stage, there is still a need for a process evaluation during the main RCT, in order to assess the implementation of the intervention, the quality and quantity of what was delivered; to provide an evaluation of the context in which the intervention was delivered; evaluate the mechanisms of impact of the intervention; and assess how an intervention can be implemented in a given context (Moore et al., 2015). Summative evaluation methods are described in detail later in the chapter.

The Purposes of Process Evaluation

There are several reasons why process evaluations are important for planning, interpreting, implementing and evaluating a psychological intervention.

(i) Planning a new psychological intervention: They enable researchers to plan new interventions, ensuring that each active intervention component is underpinned by a relevant theoretical construct. The importance of theory-driven intervention is increasingly recognised but the gap between theory and practice can be difficult to bridge. A good example of this is the field of intervention mapping, where each component of an intervention is mapped onto a theoretical construct and measured and evaluated accordingly. Intervention mapping was developed at the turn of the century, in parallel with the first attempt to define a framework for process evaluation (Bartholomew, Parcel, & Kok, 1998). There are 5 stages to intervention mapping as shown in Figure 3.2.

Figure 3.2: Stages of Intervention Mapping (Bartholomew et al., 1998)



(ii) Evaluate existing interventions: They can enable researchers to evaluate existing interventions that are already in routine use. Pragmatic formative process evaluation can help to identify the evidence base for an intervention about which several assumptions have been made (Evans et al., 2015). Explanations for the existence of such an intervention in practice may include, 'the presumed irrelevance of social equipoise; dissonant policy and research timescales; and the perception that an intervention will not confer harm' (Evans et al., 2015). The MRC's guidance for the development and evaluation of complex interventions claims that such an evaluation may not be necessary if an intervention is already in place (MRC, 2000). However, an established intervention may operate on many implicit theoretical and causal assumptions, which should be investigated. A methodological advantage of this type

of process evaluation is that it provides the opportunity for analysis within real world settings, and in turn is another method by which to capture real world complexities.

(iii) Interpretation of results: They enable researchers to explain why some interventions are effective, and some are not. Process evaluations are used to identify mechanisms by which an intervention was successful, or to identify those that prevented it from working as intended. A process evaluation can answer the important question of whether the failure of an intervention was due to the intervention itself, or the way that it was implemented. Process evaluation may be used to interpret the results of efficacy studies (those which aim to establish whether or not an intervention works under 'ideal', or tightly controlled conditions); effectiveness studies (those which aim to test whether or not an intervention works in 'real world' conditions); dissemination studies (those which evaluate how best to deliver information to enhance public health knowledge); implementation studies (those which assess how an evidence based intervention may be implemented within a specific setting); and 'scale up' studies (which aim to evaluate methods for increasing the impact of an evidence based intervention) (Flemming, Booth, Hannes, Cargo, & Noyes, 2018).

(iv) Identify mechanisms: They can help us to understand relationships between various intervention components. A process evaluation can help illuminate which of these methods was most effective in changing behaviour, and which combinations were most desirable. Active ingredients may include the therapeutic alliance, patient and participant barriers and facilitators to participation, competence of therapist and organisational factors such as staff resources and local policies. For example, a health promotion intervention may include group and individual psychological therapies such as MI, online self-help programmes and print materials such as leaflets. One UK based study compared 4 programs: a single session of individual diabetes education; 2 sessions of individual education; group education and education with CBT (Campbell, Redman, Moffitt, & Sanson-Fisher, 1996). There were no significant differences in main outcome measures between groups. A process evaluation focusing on fidelity found that patients in the CBT group did not receive follow up phone calls as per protocol over the 12-month follow up period and this helped explain the negative findings.

(v) Replication: Process evaluations enable researchers to replicate previous research to a high standard. If an intervention has been effective, it will be repeated, and a process evaluation will provide the level of detail necessary to do so. This is important when testing an intervention at multiple sites, or in a different context to that in which it was originally tested. For example, the Teaching Family Model was a treatment program for 'delinquent, abused and emotionally disturbed children' replicated in group homes across the United States and Canada between 1967-1993. Researchers implemented what they termed 'quality assurance evaluations' involving evaluation at organisational and treatment levels to ensure that the program was replicated accurately (Fixsen & Blase, 1993). A process evaluation can help researchers state whether any changes in efficacy of the intervention are due to a change of the environment in which it was implemented, or a failure of the intervention itself. It can help to answer the important question: will the intervention produce similar outcomes when applied in different settings?

(vi) Contextual application: Process evaluations illuminate how an intervention may be implemented in a given context by optimising the intervention content, leading to more efficient use of resources. The MRC and NIHR are the two largest public funding bodies of RCTs in the UK, yet they regularly fund RCTs which fail to reach recruitment targets or request time and/or financial extensions (McDonald et al., 2006; Sully, Julious, & Nicholl, 2013). Qualitative trial data can help by streamlining feasibility studies, ensuring that a new intervention is acceptable to participants, improve trial efficiency, and facilitate interpretation of findings therefore conserving resources and directing researchers towards interventions that are more likely to succeed in future trials (Donovan et al., 2002; Moore et al., 2015; O'Cathain, Murphy, & Nicholl, 2007).

A Scoping Study of the Evolution of Process Evaluation Theory

A scoping study was conducted to establish the evolution of the concept of process evaluation and provide a broad summary of frameworks used to date. The results of the study were used to develop a new framework for process evaluations of psychological interventions.

A systematic review of the literature focusing on process evaluations of psychological interventions was attempted prior to the scoping study but proved prohibitively complex for the following reasons:

(i) The number of potential search terms made defining search criteria impractical. There are myriad search terms relating to each component of process evaluation identified, for each type of intervention and for each disease group. There was also no reliable search term for a 'complex intervention.'

(ii) Many components of process evaluation had not been clearly defined. Studies may therefore have measured a component of process evaluation such as 'reach' or 'dose received' but not defined it as such. The volume of literature within each component of process evaluation became unwieldy and beyond the scope of this thesis.

(iii) Process evaluation frameworks varied in their components and were difficult to compare.

(iv) In an effort to remain inclusive, defining inclusion and exclusion criteria became impossible. The Centre for Reviews and Dissemination Handbook notes the difficulty of specifying criteria for complex interventions and that inclusion criteria should capture all studies of interest but that criteria which are too narrowly defined risk missing studies of interest, while criteria which are too broad may yield data which is too hard to compare and synthesise (Khan, Ter Riet, Glanville, Sowden, & Kleijnen, 2001).

(v) A systematic review is designed to answer one question, which may be composed of multiple objectives, not the many questions with corresponding multiple objectives posed by the development of a new process evaluation framework.

The field of process evaluation is too complex and heterogeneous in nature to facilitate a full systematic review within the scope of this thesis. The results of the scoping study yielded a 12 component framework which was then used to assess the

literature yielded from a review with much more appropriate, limited criteria. The results of this literature review are presented in Chapter 4.

The purposes of a scoping study have been defined as:

(i) To quickly map key concepts underpinning a research area and to establish the main sources of evidence available (Arksey & O'Malley, 2005)
(ii) To synthesise and analyse a wide range of research and non-research material to provide greater conceptual clarity about a specific field or topic (Davis, Drey, & Gould, 2009)
(iii) To make preliminary assessment of size and scope of research literature (Grant & Booth, 2009)
(iv) To contextualise knowledge by identifying what we do and do not know, and setting this within policy and practice contexts (Anderson, Allen, Peckham, & Goodwin, 2008)

Aims

(i) To broadly map the history of process evaluation theory
(ii) To establish the key constructs underpinning process evaluation theory
(iii) To establish existing process evaluation frameworks
(iv) To identify gaps in the process evaluation literature

Methods

Databases (Medline, Embase, and PsycINFO) and the wider evaluation literature (texts and evaluation manuals) were searched between the earliest available date and 07/2013. Studies and frameworks eligible for inclusion were published in English, and tested on humans. Reference lists of included studies were checked for eligibility. Frameworks were excluded if the authors did not explicitly state that they were carrying out a process evaluation.

Search terms included the following keywords and their medical subheadings (MeSH). The search strategy for Medline is reported in Appendix 1.

Table 3.1: Scoping Study Search Terms

Topic	Search Terms
Process Evaluation	Process evaluation, fidelity, adherence, implementation, treatment integrity, intervention integrity, evaluation study, patient satisfaction, process assessment, program implementation, program delivery
Methodology	Randomised controlled trial, qualitative, type III error, ethnography, observational, semi-structured interview
Psychological Intervention	Psychological intervention, psychotherapy, motivational interviewing, cognitive behavioural therapy, psychological therapy, psychosocial intervention, counselling, behavioural, mental health

Data Extraction

Studies included in this scoping study were defined as having conducted a process evaluation if the authors explicitly stated that they were conducting a process evaluation or process measures. Data were extracted on (i) definitions of process evaluation (ii) terms used to describe process evaluation components (iii) methods used to conduct process evaluations. Studies were excluded if the articles were not published in English. A narrative synthesis was conducted to address scoping study aims and consensus on overlapping process evaluation concepts reached with supervisors.

Results

The narrative synthesis established a brief history of evaluation theory followed by a history of the development of the concept of process evaluation. Five process evaluation frameworks were identified measuring 11 components. These data were used to propose an additional 12-component process evaluation framework.

A Brief History of Evaluation

Humans have evaluated programs informally for thousands of years, with Scriven noting that 'evaluation is a very young discipline - although it is a very old practice' (Scriven, 1996). The first records of scientific evaluation were in the field of education in 1792, when quantitative marking was introduced as a method of assessing students' work (Hoskin, 1979). Hoskin described seven periods of evaluation: Age of Reform (1792-1900); the Age of Efficiency and Testing (1900-1930); the Tylerian Age (1930-1945); the Age of Innocence (1946-around 1957); the Age of Development (158-1972); the Age of Professionalization (1973-1983) and the Age of Expansion and Integration (1983-2000) (Kellaghan & Madaus, 1982). The Age of Reform (1792-1900) introduced objective scoring, aggregating and averaging of scores, marking a period of educational reform in the UK. A quantitative marking system enabled objective ranking of examinees and the aggregating and averaging of scores. This marked a crucial initial stage in the development of the field of psychometrics and led to the recommendation that teachers' salaries be determined by students' performance in reading, writing and arithmetic (Kellaghan & Madaus, 1982). In the second evaluative stage (Age of Efficiency and Testing) from 1900-1930, there was a new focus, on improving efficiency in testing, influential for educational administrators (Worthen & Sanders, 1987) while the Tylerian age (named after Ralph Tyler, considered the father of educational evaluation) saw longitudinal research into evaluation of the effectiveness of teaching methods. Tyler found that instructional objectives could be clarified by stating them in behavioural terms. He defined academic instructions in terms of the desired behavioural results, and his work formed the basis of criterion based testing (Tyler, 1975). The Age of Innocence from 1946-57 represented a period of post-war optimism, and evaluation researchers

began to distinguish between different types of 'learner' or person being evaluated, at the same time recognising the need for tests to be designed to measure specific outcomes. Despite this progression, little funding was allocated to educational reform, hence the term Age of Innocence (Reiser, 2001). During the 1960's (The Age of Professionalisation) criterion referenced testing was introduced, which replaced norm-referenced testing with measures of individual performance on sets of established criteria, significant because it was able to measure how well an individual performed, irrespective of how well others are performing. Finally, The Age of Expansion and Integration saw the development of professional organisations and evaluation standards (Reiser, 2001).

The Development of the Concept of Process Evaluation

It was during the 1960's that the concept of process evaluation was probably first introduced, although it was not defined as such, with researchers working in health education planning defining process evaluation as, 'monitored by various means, including audit, peer review, accreditation, certification, and government or administrative surveillance of contracts and grants' (Green, 1977). Although very different to current definitions, this description highlights the importance of evaluating a new intervention or program using multiple sources of data. A textbook on evaluation described how, 'an evaluation study may limit its data collection and analysis simply to determining whether or not a programme is successful...However, an analysis of process can have both administrative and scientific significance, particularly where the evaluation indicates that a programme is not working as expected' (Suchman, 1968).

The Age of Professionalization during the 1970's saw the emergence of evaluation as a professional field with professional journals established and universities offering courses in process evaluation. Research focused on 'the issues of improving evaluation designs and measuring programme effects' and the field of process evaluation made little progress (Linnan, 2002). Major textbooks of the time made no mention of process evaluation (Glass, 1976; Green, 1977).

It was not until the 1980's that the field of process evaluation began to develop. It was described as assessing, 'whether specific elements such as facilities, staff, space, or services are being… established according to the given program plan' (Windsor, Baranowski, Clark, & Cutter, 1984) and was followed in 1985 by the publication of what is considered a key paper in the field of process evaluation research. 'Avoiding Type III Errors in Health Education Program Evaluations: A Case Study' (Basch, Sliepcevich, Gold, Duncan, & Kolbe, 1985) argued that in addition to the more familiar Type I error or 'false positive' (rejecting a 'true' null hypothesis or falsely inferring the existence of a result that is not present) or Type II Error (failing to reject a 'false' null hypothesis or falsely inferring the absence of a result that is present) there is a third error to be avoided: Type III.

A Type III Error can be defined as, 'evaluating a programme that has not been adequately implemented' (Basch et al., 1985). It occurs when implementation has not been adequately studied, leading to incorrect inferences about the efficacy of an intervention or programme. For example, in a study of a systematic care programme for caregivers of dementia patients, it was concluded that an observed difference between intervention groups may have been due to a lack of adherence to the intervention protocol (Spijker et al., 2013). Although this type of error was not new to the literature in general, this represented the first time it had been used in the public health service context (Linnan, 2002). The authors highlighted the need for trialists to consider that it is not possible to make meaningful conclusions about the efficacy of a programme without first establishing quality of implementation. This led to the evolution of the process evaluation concept 'dose delivered', which refers to how much of the intervention was delivered to participants as intended (an example of an intervention dose may constitute a session of health education encouraging participants to keep a food diary).

An important distinction should be made between a trial of clinical effectiveness and a trial of efficacy in which an intervention was not properly delivered (a Type III error). While a trial of efficacy can be defined as a trial of an intervention under ideal or controlled conditions among a highly selected homogeneous population, a trial of effectiveness is one that assesses its performance under 'real world' clinical conditions in a heterogeneous population. (Singal, Higgins, & Waljee, 2014). Efficacy

data is often assumed to represent effectiveness data when in fact an efficacy trial can often overstate an intervention's effect when implemented in clinical practice. While efficacy research maximises the likelihood of observing an intervention effect, effectiveness research may better account for external patient and provider factors such as access to services and adherence to medication, which may moderate the effect of the intervention once implemented in clinical practice (Singal et al., 2014). This gap between translation of research into clinical practice is well documented (Glasgow et al., 2003).

One of the most crucial aspects of quality of implementation is how much a dose of the intervention was *received* as intended. A dose may be delivered to participants but that does not mean it was received; for example, participants may be encouraged to keep a food diary but if they do not engage in that behaviour, the dose has not been received as intended. A dose may also be received where it is not intended, for example from a source outside of the intervention program or when an aspect of the intervention is delivered to a control group participant.

The concept of 'dose received' became defined as such due to the combined efforts of 3 different studies. These decade-long studies funded by the National Heart, Lung and Blood Institute (NHLBI) aimed to establish the effects of community education programs on cardiovascular disease and were called The Stanford Five-City Program (Farquhar et al., 1990), The Pawtucket Heart Health Programme (Carleton, Lasater, Assaf, Feldman, & McKinlay, 1995) and The Minnesota Heart Health Programme (Perry, Kelder, Murray, & Klepp, 1992). The research teams involved in these 3 studies collaborated to establish a consistent approach to measuring the dose of the intervention received by their target populations.

The Stanford Five-City Program tested whether community-wide health education can reduce coronary artery disease and stroke. The RCT compared 2 intervention cities (n=122, 800) and 2 control cities (n=197, 500) on risk factor variables including BP, plasma cholesterol, smoking rate, weight and resting pulse rate. Groups were compared on these variables at baseline and at 3 time points during a 64-month follow up period. Intervention groups received a health education intervention based on a communication-behaviour change model and social learning theory (Bandura, 2011).

At 30 and 64 month follow up significant changes favouring the treatment groups were observed in plasma cholesterol, BP, resting pulse rate and smoking rate. These changes resulted in decreases in mortality risk scores (15%) and CHD risk scores (16%) (Farquhar et al., 1990). The Pawtucket Heart Health Programme tested whether a community health education programme implemented in Pawtucket changed cardiovascular risk factors and disease risk relative to comparison communities. A total of 15,261 people aged 18-64 took part in 6 surveys over 14 years. Number of respondents for each survey ranged from 2037-2955. Projected CHD rates were lower (16%) in Pawtucket during the education programme. This difference reduced to 8% post education (Carleton et al., 1995). The Minnesota Heart Health Programme tested a community education programme in 6 communities over 10 years (n=7097). A community education programme designed to reduce cardiovascular disease risk was delivered to 3 communities. No significant differences were found in blood cholesterol level, BP, BMI or physical activity. There was a small significant treatment effect on smoking prevalence (Luepker et al., 1994).

There are many active ingredients in community education interventions. They involve multiple components (e.g. leaflets, television and radio, newspapers and direct education including face to face, group and correspondence courses) making it difficult to isolate which components have an effect, and which ones have the greatest and the least effects. Participants are located throughout the community, making data collection difficult. The large scale of such interventions makes implementation challenging, as they cannot be as tightly organised as interventions delivered to small groups or individuals. Finally, community interventions co-exist with local and national programmes, making it difficult to differentiate intervention effects from usual practice and changes in policy.

The NHLBI studies used qualitative methods (telephone surveys) to assess whether participants had actually received the dose delivered. They discovered that messages and programmes similar to those included in their community education interventions were being delivered from alternative sources, such as government agencies, healthcare providers and voluntary health organisations. They were therefore able to adjust their parameters for measuring ‘dose received’ in order to account for the extra exposure (Pirie, Stone, Assaf, Flora, & Maschewsky-Schneider, 1994). The concept

of ‘dose received’ was expanded to include the total sum of messages and programs consumed by participants. Other studies began to adopt the ‘dose delivered’ and ‘dose received’ approach (Sorensen et al., 1996).

In the early 1990’s it was suggested that process evaluation could also be used to inform the design and development of interventions, and be conducted during the lifetime of an RCT rather than consisting of post-hoc implementation assessment. The Community Intervention Trial for Smoking Cessation (COMMIT) study tested whether a community intervention can reduce the prevalence of adult cigarette smoking. One community within each of 11 matched community pairs (10 in the United States, 1 in Canada) was randomly assigned to intervention. Telephone surveys at baseline and 5 year follow up showed no intervention effect on heavy smoking prevalence. A process evaluation involved an ‘implementation evaluation’, alongside other assessments such as ‘quality control’ while the authors emphasised the ‘formative role’ that evaluation may play in research design. They suggested that there was potential for amending and correcting aspects of the design throughout the course of the intervention. They also discuss the idea that process evaluation may include both quantitative and qualitative methods (Corbett, Thompson, White, & Taylor, 1990).

Implementation Research

The field of implementation research is based on several disciplines and aims to understand what, why and how interventions work in real world settings (Peters, Adam, Alonge, Agyepong, & Tran, 2013). Implementation research may investigate any aspect of implementation, including the processes or factors that affect implementation, or the results of implementation. It also intends to test potential methods for improvement (Peters et al., 2013).

Some principles of implementation research overlap with those of process evaluation. For example implementation research focuses on the context in which an intervention is implemented, seeking to understand the environmental conditions that may affect outcome. It seeks to examine the contextual effects of real world settings, rather than

eliminate variables that may confound effects, for example excluding patients with comorbidities. A core aim of implementation research is to 'enhance the adoption of a clinical intervention' (Curran, Bauer, Mittman, Pyne, & Stetler, 2012) and as such may be concerned with any aspect of the intervention including factors which affect implementation, effects of implementation, processes of implementation and investigating how interventions are implemented in practice.

Implementation research is particularly concerned with intervention participants, who may include stakeholders such as policy makers, executive decision makers, practitioners or trial participants. Petersilia observed that, 'the ideas embodied in innovative social programs are not self-executing' and that what is needed is an, 'implementation perspective on innovation — an approach that views post-adoption events as crucial and focuses on the actions of those who convert it into practice as the key to success or failure' (Petersilia, 1990).

It may measure a number of variables including Acceptability (acceptability of the intervention to stakeholders); Adoption (the uptake of a new intervention); Appropriateness (perceived fit of an intervention); Feasibility (the practical use of an intervention); Fidelity (the extent to which the intervention was implemented according to protocol); Implementation Cost (the cost of the intervention); Coverage (the reach of an intervention) and Sustainability (ongoing adoption of the intervention) (Peters et al., 2013), which overlap with some proposed components of process evaluation.

Implementation research has been used predominantly to assess the implementation of interventions in low income areas or developing countries. For example, a systematic review of strategies to improve health service delivery in low and middle income countries reviewed 150 studies and concluded that how a strategy is implemented is as important as the type of strategy implemented, and identified a number of successful implementation strategies, with multiple strategies more effective and single and stakeholder consultation a crucial defining element (Peters, El Saharty, Siadat, Janovsky, & Vujicic).

Although implementation research has received attention over the past decade, there is considerable variation in terminology and confusion about its scope. The concept of implementation is loosely developed and 'lacks adequate specification of causal

mechanisms' (Paudel, 2009). The concept is used to refer to the process of implementation but also the output and sometimes the outcome of the implementation process (Winter, 2012).

Formalising Process Evaluation

Due to the lack of a formal framework for process evaluation, researchers within the health education context continued to independently attempt to define elements. The CATCH study, another NHLBI funded trial, examined the effect of a school based health education program on cardiovascular disease risk (Perry et al., 1990). A sample of 4019 children from San Diego, Houston, New Orleans and Minneapolis were measured for risk factors including total cholesterol, obesity and BP at baseline and 2.5 year follow up. No significant change in the primary outcome measure of total cholesterol was observed. The authors conducted a process evaluation as part of the trial, to 'assess the degree of compliance and fidelity to the CATCH interventions.' The evaluation assessed 'participation,' 'dose', 'fidelity,' and 'compatibility' (Perry et al., 1997). This represented one of the most extensive process evaluations yet conducted, covering programme implementation, monitoring of the quality of the intervention delivered, and consideration of the environmental context in which the intervention took place. However, as there was no consensus among researchers during these early studies there was some conceptual overlap between components of process evaluation studies, making replication of methods challenging.

In the late 1990's, the lack of a formal and comprehensive process evaluation framework was acknowledged by a group of American public health researchers (Glasgow et al., 1999). Outlining '5 dimensions of quality' that they considered essential to process evaluation, they formulated the quantitative RE-AIM Framework (Reach, Efficacy, Adoption; Implementation and Maintenance), designed to aid researchers in evaluating health promotion interventions. The 5 components were:

(i) Reach, concerning proportion of the target population that participated in the intervention

(ii) Efficacy, concerning the success rate if the intervention was implemented as intended, defined as positive outcomes minus negative outcomes
(iii) Adoption, meaning the proportion and representativeness of settings which adopt the programme
(iv) Implementation, referring to the extent to which the programme was delivered as intended
(v) Maintenance, or the extent to which the health programme or policy is maintained.

The 'ultimate impact' of an intervention was considered as its combined effects on these 5 evaluative dimensions. The RE-AIM framework, although overlapping with some aspects of the field of process evaluation was never actually defined as such, and despite its contribution as an attempt to formalise the evaluation process, it fails to account for the complexity of many interventions due to its focus solely on quantitative measurement.

The first attempt to define a framework for process evaluation as it is currently understood came at the turn of the century, in parallel with the development of intervention mapping. Intervention mapping aimed to aid researchers in the design and development of new interventions (Bartholomew et al., 1998). It emphasised the importance of developing interventions based on current theory first and outlined a 6-step method for planning a behaviour change intervention. A core component of the mapping process involved developing an 'evaluation model' as part of a process evaluation. The concurrent development of both intervention mapping and process evaluation fields was a response to the need for improved evaluation methods due to the growing complexity of interventions.

A step change in the methodological advances was when Baranowski and Stables developed one of the first attempts at a more comprehensive process evaluation framework (Baranowski & Stables, 2000). They defined 11 components of process evaluation based on their evaluation of the '5 a Day Projects', a large-scale nutrition intervention aimed at promoting fruit and vegetable consumption. The studies, funded by The National Cancer Institute, comprised 9 RCTs designed to increase fruit and vegetable consumption for the primary prevention of cancer. Three of the studies were conducted within elementary schools using classroom curriculums, newsletters,

videos and family activities (Davis et al., 2000) (Reynolds et al., 2000; Story et al., 2000); 1 delivered an intervention to high school students via classroom workshops, family activities and dietary change (Davis et al., 2000); 3 targeted adults via work-site wellness programmes using individual programmes using the Stages of Change Model (Prochaska, DiClemente, Velicer, Ginpil, & Norcross, 1985) and broader, organisational support networks, family activities and peer education (Beresford, Shannon, McLerran, & Thompson, 2000; Hunt, Lederman, Potter, Stoddard, & Sorensen, 2000) (Buller et al., 2000); 1 targeted rural African American adults via their church using community (Campbell et al., 2000) and individual approaches and 1 targeted mothers, training their peers as interventionists (Havas, Anliker, Damron, Feldman, & Langenberg, 2000).

They defined the components as follows:

(i) Recruitment: the number and characteristics of participants recruited
(ii) Maintenance: ensuring participants remain in the study
(iii) Context: aspects of the environment in which the intervention has been implemented
(iv) Resources: the characteristics of agencies, implementers or participants necessary to achieve intervention goals
(v) Implementation: the extent to which the intervention is implemented as planned
(vi) Reach: the extent to which the target population receives the intervention
(vii) Barriers: barriers to the implementation of the intervention
(viii) Exposure: the extent to which participants received (or were exposed to) the intervention components
(ix) Initial use: the extent to which participants conduct the intended behaviours promoted by the intervention
(x) Continued use: the extent to which participants continue to do any of those activities
(xi) Contamination: the extent to which participants receive interventions from outside the programme and the extent to which the control group receives the treatment.

Baranowski and Stables outlined a useful framework for process evaluation based on large-scale studies, however the model has not been widely used. There is some conceptual overlap, for example ‘initial use’ and ‘continued use’ have some overlap with ‘reach’ in that they measure which behaviours participants engage with as part of the intervention. Later models attempted to redefine the components of process evaluation.

In their book, 'Process Evaluations for Public Health Interventions and Research', Linnan and Steckler (Linnan, 2002), built on this work proposing a tighter framework, comprising 7 components as follows:

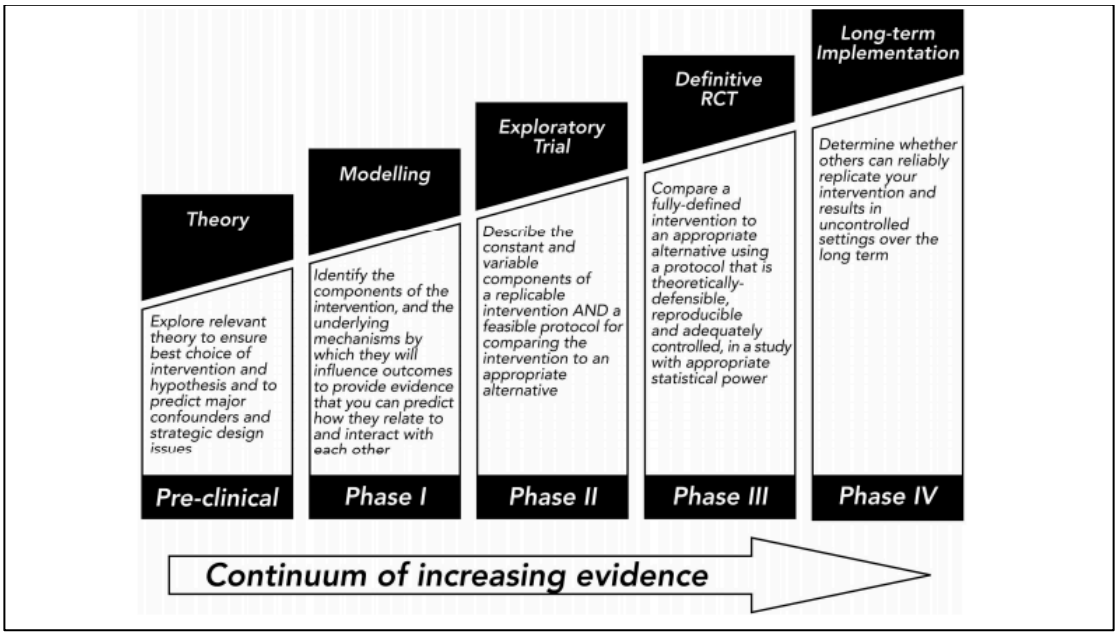
(i) Context: Aspects of the environment in which the intervention has been implemented (including the wider political and social context)
(ii) Reach: the proportion of the participants that participate in the intervention (e.g. measured by attendance)
(iii) Dose delivered: the amount of each intervention component that was delivered
(iv) Dose received: the amount of intervention actually received, or engaged with by participants
(v) Fidelity: the extent to which the intervention was delivered as planned
(vi) Implementation: a composite score indicating the extent to which the intervention was implemented and received
(viii) Recruitment: procedures used to approach and recruit participants.

Linnan and Steckler’s framework, although the most widely used, has been criticised for not paying sufficient attention to contextual variables, which may hinder or facilitate the implementation of an intervention, such as participant and therapist characteristics and behaviours (Wierenga et al., 2013). Contextual variables could be considered the most important component of process evaluation and this represents a major flaw in the model.

Acknowledging the growing field of evaluation of complex interventions and its importance, the MRC published guidelines designed to aid researchers in the development and implementation of evaluations (MRC, 2000). This document advised matching evaluation techniques to complex research designs, focused on the

development and planning of complex interventions, and the importance of evaluating the 'processes of implementation.' The authors emphasise that active components of an intervention should be identified, and recommend an, 'iterative, phased approach' to their design and implementation, using both quantitative and qualitative methods. The framework is presented as a series of steps, although some may be undertaken simultaneously.

Figure 3.3: The MRC evaluation framework (MRC, 2000)



The model begins with a theoretical phase, designed to assist researchers in developing a sound hypothesis. This may overlap with phase 1, the modelling phase, which aims to identify underlying mechanisms of the intervention. Phase II represents an exploratory phase, as aspects of the trial such as suitability of recruitment procedures and feasibility of outcome measures are tested. Phase III is the definitive or 'main' RCT testing the intervention while Phase IV represents evaluation.

Although the guide represented the first, formal guidance for researchers who wished to thoroughly plan and conduct an evaluation, it does not include any mention of process evaluation. It was criticised for its failure to recognise the complexity of contextual variation between different interventions, and for its theoretical basis,

which reflected that adopted in the evaluation of clinical drug trials (Mackenzie et al., 2010).

In the meantime, many process evaluations continued to be conducted without use of a framework. For example, one Netherlands-based evaluation of a nurse-led intervention to improve self management in patients with asthma, diabetes and heart failure through goal setting and planning of behaviour, measured patients' self efficacy and elicited patients' and nurses' perceptions of the intervention, but did not use any framework to guide the research (Schreurs, Colland, Kuijer, de Ridder, & van Elderen, 2003). Another example is a New Zealand based RCT which tested a telephone based counselling intervention designed to promote walking in a sample of 186 adults aged 65 and older, incorporating techniques drawn from CBT and MI. The authors measured participant satisfaction and views about the value of the intervention (Kolt et al., 2006). A third study conducted a process evaluation of an RCT testing the effect of a coping intervention delivered in 10 sessions, for 168 patients in The Netherlands with rheumatic diseases, which aimed to increase social support and quality of life. They evaluated patients' opinions about the content and structure of the sessions and supervisors' performance (Savelkoul & de Witte, 2001). Researchers and funders were recognising the importance of process evaluation but lacked a theoretical framework, formal guidance, examples of good practice or an evidence base to guide them.

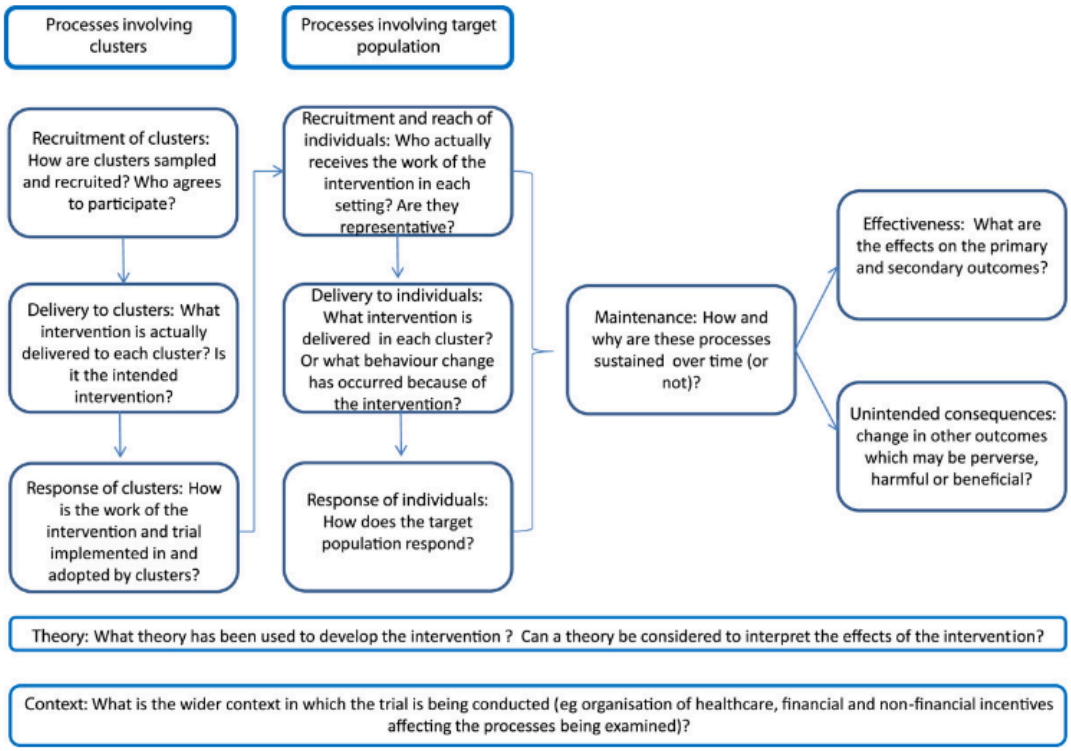
In 2008, the MRC guidance was updated (Craig et al., 2008), drawing on the expertise of researchers with experience of evaluating complex interventions plus literature review, process evaluation case studies, workshops, and discussions, which took place at conferences and seminars. Feedback was obtained via peer review and appropriate revisions made. The authors recognise that evaluation can be 'highly valuable' in assisting researchers to identify mechanisms or processes by which an intervention has worked, for assessing fidelity and quality of implementation and to identify contextual factors which may have contributed towards any variations in outcomes. They state that process evaluation, while important, is not a substitute for an outcome evaluation, but an addition to it. However, this update contained no new guidance for the development and conduct of process evaluations. There is little practical advice for researchers on how to plan and conduct a process evaluation, and the guidance has

been criticised for its failure to include theory driven approaches to evaluation (De Silva et al., 2014). Theory driven evaluation is based around a program theory, which outlines how those conducting the intervention expect it to work. It is a set of implicit assumptions that guide the design of an intervention (Chen & Rossi, 1989).

Researchers, dissatisfied with MRC guidance, began to develop individual approaches. One framework (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013) was developed as a response to process evaluation frameworks focusing too heavily on qualitative measurement, with insufficient value placed on quantitative methods. Grant et al proposed guidance for the evaluation of cluster randomised trials of complex interventions, suggesting methods for evaluating the components (Grant et al., 2013). The model is shown in Figure 3.4.

The model distinguishes between processes occurring within cluster randomised groups and individuals, then assesses maintenance of the intervention, its efficacy, and any unintended consequences.

Figure 3.4: A framework for Evaluating Complex Interventions (Grant et al., 2013)



This developed previous frameworks by suggesting suitable methodologies for assessment at each stage of process evaluation, specifying suggestions for timings of assessments. Despite this, the framework is firmly rooted in the design of the RCT and outlines only minimal process evaluation requirements.

A recurring observation in the early evolution of process evaluation research is that evaluations have been conducted in the field of community health education or education in which samples of the general population are targeted rather than individuals. This important work laid the foundation for process evaluations but some concepts could not be applied to studies that target individuals. Saunders et al recognised this problem and developed a framework for more targeted interventions (Saunders et al., 2005). They adapted Linnan and Steckler's 2002 model, providing a step-by-step plan for carrying out a process evaluation, using the example of a school based media training programme aimed at decreasing adolescent risk behaviours. They hypothesised that by enhancing students' understanding of media messages they become more able to deconstruct them and therefore more resilient to harmful messages sometimes enforced by the media (Saunders et al., 2005). They described 7 elements of process evaluation:

(i) Fidelity: extent to which the intervention is implemented as planned
(ii) Dose delivered: amount or number of intended units of each intervention or component delivered or provided by interventionists
(iii) Dose received: exposure, or the extent to which participants engaged with or are receptive to the intervention
(iv) Dose received: satisfaction, or the extent to which the participants are satisfied with the programme and its elements
(v) Reach: participation rate
(vi) Recruitment: the procedures used to approach and attract participants
(vii) Context: aspects of the intervention, which may influence outcomes.

They provided examples of qualitative and quantitative methods that could be used to carry out the evaluation and emphasised that process evaluation can be used for both the development and evaluation of interventions.

Despite this representing one of the most comprehensive frameworks to date, the work is limited by the fact that it is illustrated using the example of a fictional case study, not tested on a real world intervention. The model also lacks narrative clarity, as it does not present a clear step-by-step process for the conduct of process evaluation, for example recruitment is presented at the end. As a result, the framework has not been widely used. Many process evaluation studies combined the various frameworks to compensate for the fact that none fully met their needs. For example, a process evaluation of a year long non-randomised community based mental health promotion intervention for 11-14 year old refugee children in Beirut focused on promoting the mental health of the children and increasing their attachment to school. They based the elements of process evaluation on Linnan and Steckler's framework while the methodologies used were guided by Saunders et al (Nakkash et al., 2012). They measured the process evaluation components of 'fidelity, dose delivered, dose received and reach' but did not measure the components of 'recruitment' or 'context'. Another study used both the frameworks set out by Linnan and Steckler (Linnan, 2002) and Baranowski and Stables (Baranowski & Stables, 2000) to guide their process evaluations, while referring to the guidelines of Saunders et al (Saunders et al., 2005) to plan.

The Depression in Elderly With Long-Term Afflictions (DELTA) trial was a low intensity psychological intervention designed to reduce depression in elderly people living in The Netherlands with long-term conditions. The intervention was based on principles of CBT and self-management and was delivered by nurses to 183 elderly people with diabetes or COPD who screened positive for depression. Process evaluation questions were formulated in questionnaire format by translating 'key theoretical elements' of the frameworks described by Linnan and Steckler and Baranowski and Stables. They studied the process evaluation elements of reach, fidelity, dose received (exposure and satisfaction) and barriers (Jonkers et al., 2007).

While statisticians and epidemiologists once dominated this field of evaluation, now a more collaborative approach has been adopted. This is due to growing awareness of complex interventions in health settings and increased pressures of long-term conditions and disabilities, which require non-pharmacological approaches.

Bringing us into the 21st century, there has been slow but steady progress. Recognising the need for formal guidance in how to conduct process evaluations, the MRC published 'Process Evaluation of Complex Interventions' in 2015 (Moore et al., 2015). The guidelines built upon the previous framework for evaluating complex interventions, which had failed to mention process evaluation. The guidelines focused on three themes of process evaluation:

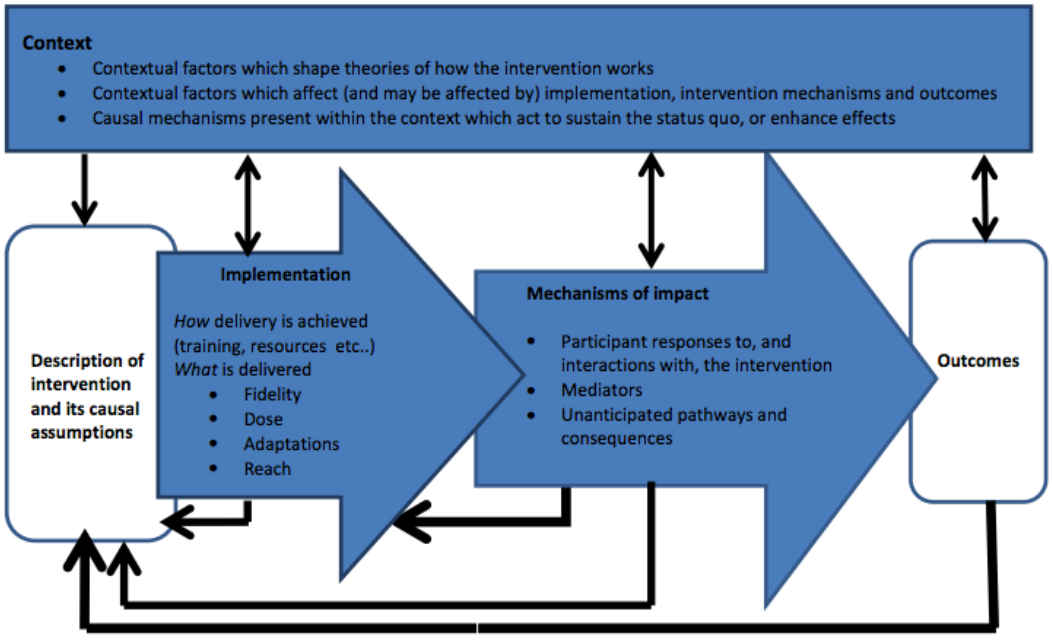
(i) Implementation of complex interventions and the methods used to do so

(ii) The mechanisms of impact: how does the intervention delivered produce change?

(iii) Context: how does context affect implementation and outcomes?

The MRC model of process evaluation is shown in Figure 3.5.

Figure 3.5: MRC 'key functions' of process evaluation, reproduced (with permission) from Process Evaluation of Complex Interventions: a Summary of Medical Research Council Guidance (Moore G, 2014)



The MRC guidelines stress that there is no 'one size fits all' set of methods for process evaluation, which has resulted in a set of guidelines that may be difficult to apply to specific research designs. Rather than providing a series of steps to follow or

processes that should be measured, the MRC model is cyclical. There remains a need for a clear, simple checklist for researchers to use when planning and implementing process evaluations, in the style of the CONSORT checklist for the reporting of RCTs otherwise there is a risk of a process evaluation becoming unwieldy, more time consuming and expensive than conducting the RCT itself. However it could also be argued that a good process evaluation of a pilot or feasibility RCT is essential to ensure the validity of a definitive RCT. The CONSORT and process evaluation checklists should be used in parallel, guiding researchers on the measurement of processes and use of mixed methodologies. The MRC is in the process of updating its guidance, due for publication in 2020 (Skivington et al., 2018).

The scoping study described the development of the concept of process evaluation, existing process evaluation frameworks, their conceptual components and methods. Gaps in the literature and a need for an easy to follow framework for the design and conduct of evaluations was revealed.

A Framework for Planning, Designing and Conducting a Process Evaluation

The results of the scoping study were used to develop a new framework for process evaluations of psychological interventions.

The methods used to develop the framework are as follows:

(i) The scoping study described above established current process evaluation frameworks, conceptual components, methodologies used and gaps in the application of process evaluation components to psychological interventions
(ii) Overlapping concepts within each framework were mapped (Table 3.2)
(iii) The key elements of the frameworks identified are synthesised in the 12-component framework described below.

This framework was applied as a method of summarising the literature described in Chapter 4 (literature review)

Table 3.2: Components of Process Evaluation Measured by Most Commonly Cited Frameworks

	Baranowski & Stables 2000 (Baranowski & Stables, 2000)	Linnan & Steckler 2004 (Linnan, 2002)	Saunders et al 2005 (Saunders et al., 2005)	Grant et al 2013 (Grant et al., 2013)	MRC Guidance 2015 (Moore et al., 2015)
Formative Process Evaluation				X	X
Recruitment	X	X	X	X	
Maintenance	X			X	
Context/Resources	X	X	X	X	X
Implementation/Fidelity	X	X	X	X	X
Reach/Dose Delivered	X	X	X	X	X
Barriers and/or Facilitators	X				X
Exposure/Dose Received/Initial Use	X	X	X	X	X
Mechanisms of Impact					X
Continued Use/Adoption & Maintenance	X				X
Contamination	X				

Baranowski and Stables (Baranowski & Stables, 2000) produced the framework with the most components, closely followed by the MRC's recent guidance (Craig et al., 2008). The fewest components were defined by Linnan and Steckler (Linnan, 2002), and Saunders et al (Saunders et al., 2005).

The Components of Process Evaluation

1. Formative Process Evaluation

Formative Process Evaluation takes place prior to the main RCT and is used to plan and assess feasibility of a new intervention before it is tested. It is concerned with the way that theory maps onto different intervention components and has similarities with the field of intervention mapping (Bartholomew et al., 1998) but differs in that theoretical components may not necessarily be formal academic theories. All interventions are 'theories incarnate' (Pawson, Greenhalgh, Harvey, & Walshe, 2005)

in that they represent a combination of theoretical beliefs that the actions of the intervention will lead to the desired outcome. It is commonly recommended that public health interventions should be based on formal behaviour change theory (NICE, 2014). However, many formal behaviour change theories are in fact weak predictors of behaviour (Bartholomew et al., 1998; Shepperd et al., 2009) and interventions which are based on formal theory are not always more effective than those which are not (Eakin et al., 2014). For example, a meta-analysis of behaviour change interventions based on the Theory of Planned Behaviour (Arkes et al., 1991; Van Lange, Kruglanski, & Higgins, 2011) concluded that effect sizes for interventions varied across behavioural domains (Steinmetz, Knappstein, Ajzen, Schmidt, & Kabst, 2016). Each theoretical construct should be identified and specified clearly, mapped onto a component of the intervention and plans for evaluation made accordingly.

Pragmatic Formative Evaluation may be used to establish an evidence base for an intervention that is already in routine use within a healthcare organisation and about which a number of assumptions relating to theoretical underpinnings and mechanisms of action have been made but have not yet been formally established (Evans et al., 2015).

2. Acceptability and Social Validity

The *Acceptability and Social Validity* stage of process evaluation represents a second phase of formative process evaluation, concerning whether or not an intervention is feasible and acceptable to its potential participants. It involves any pilot or exploratory studies that aim to assess feasibility of a full trial. It may also involve obtaining feedback from a population with demographics representative of the potential trial sample, for example via patient participation and involvement groups (PPI). In the UK the use of PPIs in healthcare and social policy research is well established, and their value recognised in terms of empowering patients and informing development of healthcare services (Health, 2010). The aim has been to move towards a more patient centred service and to give insights, which can contribute to the planning and design of an intervention. For example, a 2012

systematic review (Brett, 2012) found that the positive impacts of PPI groups during the planning stages of research were that they helped to identify user-relevant topics for the research agenda and helped to prioritise research topics. They also offered pragmatic criticism of research protocols and gave feedback on the extent to which they felt the research to be relevant or appropriate. Examples of this included culturally relevant issues that should be accounted for when undertaking a study in certain settings. For example, the Diabetes Interventions Reaching and Educating Communities Together (DIRECT) study aimed to identify levels of diabetes-related burden among African American communities in North Carolina. However, suspicion of federally funded research among African American communities has made this difficult, due to instances of historical exploitation and abuse in medical and public health research (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999).

Researchers used PPI at the pilot stage to aid researchers in gaining valuable data on the health behaviours of an African American sample. A community advisory board was formed, comprising members with a broad representation of the community's civic, religious, social and professional spheres. The board reviewed the acceptability of the program materials and methodology, and advised on methods to encourage participation. Data were also collected on health status and it was found that African Americans were more likely to smoke and have uncontrolled hypertension and were less likely to have a single health provider. This data enabled researchers to refine methodologies and identify areas for intervention in the main study protocol (Engelgau et al., 1998).

3. Recruitment

The recruitment stage of evaluation concerns the strategies used to recruit patients and their potential effects on study outcome. Recruitment strategies may often be discussed as a limitation of an RCT post-trial but not as a stage of evaluation. The *Acceptability and Social Validity* formative evaluation stage may feed into the analysis of *Recruitment* strategies via the use of patient participation. For example, it has been found that PPI groups may assist recruitment by providing greater access to research communities (Faulkner, 2006; Rhodes et al., 2002) and by identifying the

most effective ways of accessing participants (Hanley, Truesdale, King, Elbourne, & Chalmers, 2001; Wyatt et al., 2008). For example, researchers working on the Diabetes Interventions Reaching and Educating Communities Together (DIRECT) study maximised recruitment of participants by offering them an extended medical examination in addition to blood glucose screening and BP measurement. This enabled participants to view the program as a health service to meet their needs rather than research activity to meet the needs of researchers. The research team worked closely with the community to provide resources for individuals who did not have or could not afford regular medical care (Burrus, Liburd, & Burroughs, 1998). Service users may also provide valuable information on the wording and appropriateness of recruitment documents such as patient invitation letters and patient information sheets. For example, researchers working on the DIRECT study changed participant information sheets and other printed materials to fifth and sixth grade reading level to ensure they were written in language that could be understood by all participants, therefore maximising recruitment potential (Paterson, 2004) (Burrus et al., 1998).

4. Dose Delivered

This refers to the number or amount of intervention units that were delivered to the participants as planned and represents one of the first process evaluation constructs ever defined in the literature (Linnan, 2002). This component of process evaluation is required for the conduct of any RCT as per step 13a on the CONSORT checklist (Begg et al., 1996). *Dose Delivered* refers to the proportion of units of the intervention that were delivered as intended, and is therefore directly related to intervention implementation. Researchers should establish a priori what the acceptable proportion of dose received should be. While in a medicinal trial this is relatively straightforward to quantify it becomes more complicated in psychological interventions.

5. Dose Received

A dose of an intervention may be delivered to a participant, but that does not mean that it has been received. A *Dose Received* is that which is actively 'used' or 'engaged with'. In medicinal RCTs measuring dose received is relatively straightforward, for instance via prescription charts, measuring the presence of a drug or biomarker in the blood, urine or other bodily fluids or tissues. In psychological interventions *Dose Received* has also been termed 'exposure' in the process evaluation literature (Baranowski & Stables, 2000). For example, a participant may fail to attend a session of MI or be late for it, and will therefore not receive any therapeutic dose.

Dose Delivered + Dose Received is equal to the concept of Adherence. If the minimum acceptable level of an intervention was delivered to a participant and it is accepted that they also received each dose then it is reasonable to conclude that the minimum amount of intervention required has been delivered as intended.

6. Programme Implementation/Fidelity

This represents the extent to which the intervention was delivered as planned in the protocol. It explores the difference between the planned intervention and the delivered intervention (Bond, Evans, Salyers, Williams, & Kim, 2000; Dusenbury, Brannigan, Falco, & Hansen, 2003). For example, a physical therapist may be trained in the delivery of a novel intervention for the recovery of movement after stroke. However, if they do not perform the intervention technique as specified during training, or they do not reach competency in that technique, they have not maintained treatment fidelity. Fidelity may represent the most difficult process evaluation component to assess accurately due to the wide range of methods used to assess it - which are both qualitative and quantitative - and the subjective nature of quality ratings. For example, even a standardised questionnaire such as the Motivational Interviewing Treatment Integrity scale (MITI) (Moyers, Martin T Fau - Manuel, Manuel Jk Fau - Hendrickson, Hendrickson Sm Fau - Miller, & Miller, 2005a) relies on some subjectivity on the part of the rater. This can be minimised by multiple ratings and assessment of inter-rater reliability but this is very time consuming and expensive work.

Measuring fidelity can also help to identify new or unexpected mechanisms of change. When testing any new intervention there is potential for disagreement about how and why change may occur. Using a behavioural rating system to assess the therapist's fidelity to various aspects of MI can identify which components of therapy were most used and were therefore most likely to have influenced outcome.

7. Contamination

Most psychological interventions cannot be delivered blind to the participant or the provider and therefore it is difficult to ensure delivery is contained only within the intervention arm. This is especially the case with psychological interventions where the participant has to be aware of receiving talking therapy and of course the therapist and in that context so is everyone in the social network e.g. family, friends, other health providers. Contamination is defined by Keogh et al as, 'the process whereby an intervention intended for members of the trial (intervention or treatment) arm of a study is received by members of another (control) arm' (Keogh-Brown et al., 2007).

8. Provider Experience

This concerns the experiences of the provider selected to deliver the intervention. There are many individual characteristics with the potential to affect outcome, including provider responses; personal beliefs and values; previous experience or training and capacity to engage. The complexity of psychological skills training means that many factors may combine to influence delivery of the intervention, and therapists may experience barriers such as concerns about workload, time barriers and need for specialist staff (Prytys, Garety, Jolley, Onwumere, & Craig, 2011). This also concerns provider satisfaction and the acceptability of the intervention to providers. The data gathered at the formative *Feasibility and Social Validity* stage can be compared with post-trial data collected from participants and any discrepancies explored. Provider experience is assessed in this thesis as process evaluation 6.

9. Participant Experience

This concerns the experiences of participants who receive the intervention, their satisfaction and the degree to which they find the intervention acceptable. There are many individual characteristics with the potential to affect outcome, including participant responses; interaction between participant and interventionists; personal beliefs and values; previous experience or training and capacity to engage. For example, in a RCT of behavioural counselling in newly diagnosed T2D, diet was as effective as diet and exercise in improving glycaemic control. However, exit interviews with participants revealed that this was probably because the latter rewarded their exercise with more food which may explain why greater 'dose' arm (diet plus exercise) was as effective as diet alone (Andrews et al., 2011; Malpass, Andrews, & Turner, 2009). One interpretation of these findings is that adding exercise does not improve effectiveness but an alternative interpretation is that by adding additional behaviour change techniques or education, the patient could be supported in not 'rewarding' themselves after exercise thus potentially leading to an increased effect. This is an example of the power of process evaluation.

The data gathered in the formative *Feasibility and Social Validity* stage can also be compared with post-trial data collected from participants and any discrepancies explored.

10. Context

This refers to the environmental setting in which the intervention is implemented that have the potential to affect outcome. These may include organisational factors such as management structure within the setting where the intervention is being tested, for example the hierarchy of healthcare professionals within a hospital outpatient department or GP surgery; systems and logistical factors such as the communication channels within teams, for example the methods of referral within a hospital triage system or political factors such as local or wider national policies and economic factors such as available funding and resources. For example, a longitudinal study which followed up 314 fourth-year UK medical students over 11 years found a lack of sufficient resources and tensions between colleagues within an organisation may lead

to high levels of stress and result in decreased quality of patient care (Firth-Cozens, 2001).

11. Barriers and Facilitators

Barriers and facilitators may be revealed as a result of exploring other components of process evaluation such as *Participant Experience* or *Context*. For example, one qualitative study explored barriers to adoption of a Telecare health system for elderly people. A Telecare health system is a remote method of monitoring changed in an individual's environment, for example sensors to detect falls, flooding or gas (Bower et al., 2011). Reasons for study withdrawal included that the intervention was too time consuming and that patients missed the routine of their previous treatment. In addition, participants described barriers to participation, which were phrased in terms of potential threats to their identity, independence and self-care. The study revealed therefore that it may be valuable to address such concerns at the beginning of an RCT, in order to maximise participation (Sanders et al., 2012).

12. Adoption

An intervention may be successful but is not useful if it cannot be translated into practice. Researchers should consider the resources needed in order for a programme to be adopted long-term. What can the process evaluation tell us about whether this might be possible? Identifying the active ingredients that contributed towards the success of an intervention is essential if the intervention is to be replicated and adopted. For example, the Diabetes Prevention Programme (DPP) was a large RCT which tested whether lifestyle intervention or pharmacological therapy would prevent or delay the onset of diabetes in people with impaired glucose tolerance (Group, 2002). The lifestyle intervention was administered to 1,079 participants and was highly effective, with a 58% reduction in the incidence of T2D. A key feature of the intervention that contributed towards the successful outcome was intensity. Methods used included individual lifestyle coaching delivered in 16 x 30 minute sessions over 24 weeks; behavioural self-management strategies; supervised physical activity with free gym membership; adherence strategies; ethnically tailored material and an

extensive support, training and feedback network. This intervention was effective but was not suitable for direct translation into practice as it was a) resource heavy b) the sample was not representative as participants were highly selected and c) the intervention was delivered within an expert multi-disciplinary team. The intervention was designed for efficacy and not community implementation (Ackermann & Marrero, 2007; Garfield et al., 2003). However, NHS England is currently rolling out a version of the DPP called 'Healthier You' as a pilot digital phase. Up to 5000 patients with non-diabetic hyperglycaemia will be recruited over 6 months and offered access to digital interventions for 12 months. Digital intervention strategies include wearable exercise monitors; health coaching apps; online peer support groups and the ability to monitor and set goals electronically. Online self-monitoring may have the same impact as face to face interventions (NHS England, 2018).

Process Evaluation Methodology

A process evaluation assesses multiple components, using multiple methodologies, which may be quantitative and qualitative. Process evaluation research has evolved, moving from the use of occasional qualitative methods after the conduct of RCTs (Lewin, Glenton, & Oxman, 2009) to the use of mixed methods, and there is increasing evidence that the use of both quantitative and qualitative methods together can facilitate deeper understanding (Curry, Nembhard, & Bradley, 2009; O'Cathain et al., 2007; Snowdon, 2015).

The use of multiple methodologies in research is often termed 'triangulation' (Campbell & Fiske, 1959; Jick, 1979) referring to a method of cross validation, where sets of results using different methods are found to be congruent, yielding comparable data. Triangulation can be used to evaluate complex interventions via the use of both quantitative and qualitative methods. For example, when exploring the reasons why a psychological intervention did not work, it may be noted by observers of therapist training that some therapists appear less confident than others, and this finding may be corroborated by a questionnaire which reveals that self-efficacy among those therapists is low, providing a more nuanced and hopeful interpretation of the observed findings. The use of mixed methods is therefore an important feature of process

evaluation, and wherever possible, both quantitative and qualitative methodologies should be used. This is in line with the current view that quantitative and qualitative methods can be complementary rather than rival sets of methodologies, since a greater number of viewpoints allows for greater accuracy of results (Jick, 1979). The use of multiple methods however does not mean that the data must be synthesised, but rather that it should be used to build a more complete picture. There is much debate about the advantages and disadvantages of attempting to combine data collected using quantitative and qualitative methods however and some researchers suggest that these two paradigms may be more useful as complementary perspectives, rather than in combination (Sale, Lohfeld, & Brazil, 2002). In the following section, a description of methodological approaches to process evaluation is given. These methods are summarised in Table 3.3.

Table 3.3: Proposed Summary of Dimensions and Methodologies to Consider in a Process Evaluation

Process Evaluation Component	Description	Quantitative Methods	Qualitative Methods
Formative Process Evaluation	Mapping of theory to intervention	Feasibility study	Literature review Ethnography Intervention mapping
Acceptability and Social Validity	Establishing feasibility and acceptability of the intervention from potential participants' perspectives.	Feasibility Satisfaction Questionnaire	Interview Focus group
Recruitment	How may the recruitment process selected cause participation bias?	Feasibility study	Literature review
Dose Delivered	The amount of intervention delivered to participants.	Checklist records of dose delivered Structured observation	Audiotapes of sessions
Dose Received	The amount of intervention received by participants.	Behavioural coding systems e.g. MITI Questionnaire Structured observation Virtual monitoring e.g. digital feedback	Audiotapes of sessions Focus groups Interviews Observational monitoring e.g. shadowing staff
Program Implementation/ Fidelity	The extent to which the intervention was delivered as intended.	Behavioural coding systems e.g. MITI Questionnaires Structured observation	Audiotapes of sessions Observational study
Contamination	The extent to which the intervention was contaminated by other sources, or the extent to which the control group received the intervention.	Randomised controlled trial design	Interview Focus group Observational study
Provider Experience	The experience of providers.	Questionnaire	Interview Focus group
Participant Experience	The experience of participants.	Questionnaire	Interview Focus group
Context	The wider organisational and societal context that the intervention is taking place within.	Local policy checklists Service use data	Ethnography Interview Focus group Policy review Observational study
Barriers and Facilitators	Aspects of implementation that hindered or contributed to the success of the intervention.	Statistical analysis Questionnaire	Interview Focus group Observational study
Adoption	Considerations of the potential for long-term implementation of the intervention as a result of the process evaluation.	Synthesis of RCT and process evaluation findings	Interview Focus group Synthesis or comparison of RCT and process evaluation findings

Quantitative Measures Used in Process Evaluation

A well-designed process evaluation framework should encompass both quantitative and qualitative methods.

1. Treatment Satisfaction Using Structured Questionnaires

Structured questionnaires may be self-report or administered by a researcher. Their advantage is that they are simple to use, cheap and convenient. However, self-report questionnaires in particular may be subject to social desirability bias (Van de Mortel, 2008) whereby people choose to present a favourable image of themselves rather than provide a true response in order to please the therapist and researchers. This may also apply in the case of self-report rating scales for therapists delivering a psychological intervention, whereby the participant may be reluctant to indicate that the therapists did not perform a task as expected. They are therefore unreliable reporters of their own behaviour and that of their therapists. Questionnaires may also be used to explore the amount of an intervention received by participants. For example, a therapist may report that an intervention dose has been delivered as intended, but a participant questionnaire may indicate that the intervention dose was not received, for example if a patient is asked whether they completed homework set for a CBT session. If possible, established reliable and valid measures should be used, and where new measures are devised for the purposes of the research their psychometric properties need to be optimised before use.

2. Fidelity Using Behavioural Coding Systems

Coding of behaviour is the gold standard measurement for rating fidelity of implementation of psychological interventions. A sample of audiotaped intervention sessions may be selected and rated using a behavioural coding system such as the MITI (Moyers et al., 2005a) designed to measure fidelity to the practice of motivational interviewing or the Behaviour Change Counselling Index (BECCI)

(Lane et al., 2005) designed to measure fidelity to the practice of CBT. These data can be used to identify how much of the intervention was delivered as planned and identify mechanisms for change. Advantages of these coding systems include that they are useful in clinical settings where rigour in supervision and evaluation is needed and the fact that they measure specific clinician behaviours. Another advantage of the MITI is the rating of clinician empathy, a core characteristic of MI. The MITI has also demonstrated acceptable psychometric properties across a variety of research settings (Campbell et al., 2009) (Martino, Ball, Nich, Frankforter, & Carroll, 2008) (Turrisi et al., 2009). A disadvantage of these systems is that rating remains subjective, although this problem can be addressed via the assessment of inter-rater reliability. The systems are also useful where it is inappropriate for an observer to be present during the intervention session.

Structured observation may also be used. Intervention sessions are observed by a trained rater who records data on intervention delivery using a structured coding form. A disadvantage of this method is the Hawthorne Effect, or the fact that participants will alter their behaviour as a result of the knowledge that they are being observed (McCarney et al., 2007). This is not likely in the case of observing therapists however, as if they have not reached competence prior to observation, they are unlikely to do so simply as a result of being observed. Observation also has the potential to improve therapists' performance. This method may be inappropriate in the case of one-on-one sessions, where the presence of an observer may alter the therapeutic alliance and introduce a measurement bias.

3. Assessing Dose Delivered, Dose Received and Recruitment with Secondary Analysis of Routine Data

Secondary analysis of routine data may include, for example, the analysis of service use records, which can be used to measure *Dose Delivered and Dose Received*. An advantage of using such data is that it avoids potential bias and also has the benefit of providing a large amount of data at no extra cost. Reliability and validity of the data is a concern however, since it is not always possible to ascertain by whom and under what circumstances the data were collected. Examples of secondary service use data

may include records of patient attendance at appointments; pharmacy prescription data; GP routine data such as that collected for Quality and Outcomes Framework (QoF) (Calvert, Shankar, McManus, Lester, & Freemantle, 2009); hospital bed utilisation data; vaccination records and other electronic health records or 'big health care data' (Schneeweiss, 2014).

Qualitative Measures Used in Process Evaluation

1. Intervention Mapping

Intervention mapping relates to the mapping of theoretical constructs onto active components of the intervention. All interventions are 'theories incarnate' (Pawson et al., 2005) in that they represent a combination of beliefs about theory that the actions of the intervention will lead to the desired outcome. Each theoretical construct should be identified and specified clearly, mapped onto a component of the intervention and plans for evaluation made accordingly. An example of an intervention that has been mapped onto a theoretical model is MI, which is based on the Transtheoretical Model of Change (Prochaska & DiClemente, 1982) (DiClemente & Prochaska, 1998). This biopsychosocial model conceptualises the process of intentional behaviour change. It integrates key constructs from other behaviour change theories into a wider model of health behaviour change. The model posits 6 core constructs that represent different stages of change including (i) Precontemplation (no intention to take action within the next 6 months) (ii) Contemplation (intend to take action within the next 6 months) (iii) Preparation (intends to take action within the next 30 days and has taken some behavioural steps towards this action) (iv) Action (changed overt behaviour for less than 6 months) (v) Maintenance (changed overt behaviour for more than 6 months) (vi) Termination (no temptation to relapse and 100% confidence). Stages of change may occur in linear sequence although non-linear progression and regression to former stages is also common. The model has been criticised for its inability to capture the complexity of health behaviours. For example physical activity is not a single behaviour but a category of different specific actions including leisure, work and sport activities. People may hold different beliefs about self-efficacy for example in relation to these different categories of activity (Brug et al., 2004). A further

criticism includes the fact that the stages are based on arbitrary time periods, which has implications for matching the theory to an intervention such as MI. For example, a smoker who plans to stop smoking is in the preparation stage if this is within the next 30 days (provided they have made a quit attempt that lasted 24 hours in the past 12 months) but only the contemplation stage if it is in 31 days' time. If the stages are not qualitatively distinct, there is no reason to predict that different factors will influence different stage transitions (Sutton, 2001). The model also ignores the formation of habit through systems of punishment and reward. These are processes which operate outside of conscious awareness and therefore do not follow the conscious decision-making process outlined in The Transtheoretical Model (Robinson, 2003). Finally, a major flaw of the model is the lack of evidence to support it and studies have shown that the model is no better at predicting behaviour than a question which asks, 'are you planning to change your behaviour?' (Abrams, Herzog, Emmons, & Linnan, 2000).

There is now general consensus that MI lacks a coherent theoretical underpinning. It was not derived from theory but arose from principles underlying intuitive clinical practice (Hettema, Steele, & Miller, 2005). However, several additional theoretical influences contributed to its development including (i) Rogers' Client Centred Counselling where the main agent of change is the therapist rather than a specific treatment method (Rogers, 1951) (ii) Cognitive Dissonance Theory which describes the discomfort that results from an incompatibility between two currently held cognitions or a belief and a behaviour (Festinger, 1962) (iii) the Theory of Psychological Resistance which holds that a threat to, or loss of a freedom, motivates the individual to restore (or maintain) that freedom (Brehm, 1966) and (iv) Bandura's concept of self-efficacy which is the belief that one is capable of achieving desired goals (Bandura, 2011). More recently, Self Determination Theory has been proposed as an alternative theoretical rationale for an enhanced understanding of the mechanisms of MI. The foundation of the theory is that people have a natural curiosity about the world and a desire to better themselves. The theory proposes that behaviours lie along a continuum of autonomy, which reflects the extent to which a person is committed to a behaviour. The MI practitioner supports the person to become more autonomous (Markland, Ryan, Tobin, & Rollnick, 2005).

A related method for specifying the proposed active ingredients of a complex intervention is Behaviour Change Technique (BCT) Taxonomy (Michie et al., 2013). This consensually agreed hierarchical taxonomy of techniques may be used at the *Formative Evaluation* stage. The taxonomy consists of 93 distinct BCTs, which were agreed by expert consensus. Work is currently being undertaken to link the taxonomy to theoretical underpinnings of complex interventions (Michie, 2016).

2. Focus Groups or Group Interviews

Focus groups and group interviews gather large amounts of data in one session, which can give insights into the range and diversity of participants' attitudes, experiences and feelings in an efficient manner. It may also reveal group complexities or the intricacies of group dynamics. However, there is the potential for participants to be influenced by one another and to change their views according to social desirability and suggestibility depending on their personality types. The data collected are also limited to the topic guide and skills of the interviewer's coding and interpreting. Some participants may also be more dominant or reserved than others, limiting their potential. This may lead to a bias where the views of some participants are under represented. These data also need to be collected soon after the intervention has been administered to participants in order to ensure maximum recall of information. While the interview is an efficient use of patient and researcher time, analysing and interpreting the data is time consuming and vulnerable to researcher biases too.

3. Semi Structured Interviews

Individual interviews with participants or providers offer an opportunity to collect some of the most in depth and valuable data. They allow for the researcher to explore an individual's experience of an intervention and offer great flexibility, particularly where interviews are semi structured, with open ended questions which allow for follow up prompting and probing. They are particularly useful when there is a concern that a group situation may prevent a respondent from providing a truthful answer. They may also be used prior to the commencement of an RCT as part of consultation with stakeholders and programme interventionists to provide valuable

data on feasibility and acceptability. Despite these advantages however, they can be time consuming and costly as a large amount of data must be collected and analysed.

4. Unstructured Observation

This differs from quantitative structured observation in that the observer does not make use of a checklist or rating scale with which to record observed behaviour. Observers may make field notes about the process of training therapists in a new psychological intervention, for example, or they may be gatekeepers such as employers who have observed the impact of a new referral system on the structure and dynamic within their organisation. A further example may be the observations of regional policy makers or coordinators who are able to make broader observations. A disadvantage of this method is that ratings are subjective.

5. Ethnography

Ethnography is a methodology that allows the observation of participants in a natural, real world setting. The aim of the method is to collect data in as natural a setting as possible, as people go about their day-to-day lives. An example of this may include observing a stroke unit, and may include real time data collection from one participant, or with several of their colleagues. This method may be most appropriate at the feasibility stage of a process evaluation, where it can provide insight into the real world setting in which an intervention will potentially be implemented.

A summary of the 12 process evaluation components, their definitions and matching quantitative and qualitative methodologies can be found in Table 3.3. A checklist for researchers designing a process evaluation can be seen in Figure 3.6.

Systematic Review (Quantitative or Qualitative)

A systematic review may be either quantitative or qualitative and aims to answer a specific research question by systematically identifying, selecting and critically appraising all research within a specified area. It is used prior to the RCT to provide

an overview of the field of study and help identify gaps in the literature. There is well established guidance for conducting these reviews, including the PRISMA statement (Preferred Reporting Items of Systematic Reviews and Meta-Analyses) (Moher, Liberati, Tetzlaff, Altman, & Group, 2009) . PRISMA is an evidence based minimum set of items for reporting in systematic reviews and meta-analyses. It comprises a checklist and flow diagram, which delineate clear steps and requirements for researchers undertaking a review of RCTs.

Qualitative systematic reviews are less common but their presence in the literature is growing, with the first qualitative systematic review published in The Cochrane Database in November 2013 (Gülmezoglu, Chandler, Shepperd, & Pantoja, 2013). Guidance on synthesising quantitative and qualitative data has since been published (Siddaway, Wood, & Hedges, 2019)

Figure 3.6: Process Evaluation: A Proposed Checklist for Researchers

Process Evaluation Component	**Question**	**Completed**
1a: Formative Process Evaluation	How do theoretical constructs underpin intervention components?	☐
Methods Used……		
1b: Assess Acceptability/Social Validity	Is the proposed intervention feasible and acceptable to potential participants?	☐
Methods Used…….		
1c: Recruitment	How will strategies used to recruit participants potentially affect outcome?	☐
Methods Used…….		
2a: Dose Delivered	How much of the intervention was delivered to participants as planned?	☐
Methods Used…….		

2b: Dose Received — How much of the intervention was actually received by participants? ☐

Methods Used……

2c: Fidelity of Implementation — How far did the therapist implement the intervention as planned? ☐

Methods Used……

3e: Contamination — Was there contamination between experimental groups? ☐

Methods Used……

3b: Provider Experience — What can be learned from the experience of providers? ☐

Methods Used……

3a: Participant Experience — What can be learned from the experience of participants? ☐

Methods Used……

3c: Context — What can be learned from exploration of the environmental and societal context? ☐

Methods Used……

3**d:** Barriers and Facilitators	What were the barriers and facilitators to intervention implementation?	☐

Methods Used……

3f: Adoption	What can the process evaluation tell us about whether a programme can be adopted long-term?	☐

Methods Used……

Strengths and Limitations of Scoping Study and Framework Development

The scoping study, which summarised the history of the field, established the most commonly used frameworks, identified overlapping concepts and gaps in the field was informative as it identified recurrent themes for conducting process evaluation which could be synthesised into a proposed framework. A more comprehensive systematic review was attempted but for reasons of complexity described earlier in this chapter, was not feasible.

The advantage of this scoping study is that a broad range of evidence was summarised and synthesised in a way that would not have been possible with a tightly defined set of criteria. This is an appropriate method for summarising an emerging area of literature where data cannot be standardised and synthesised in the conventional methods required for formal systematic review.

While a scoping study provides a broad overview of a poorly defined area of research, it is likely that this approach excludes studies of interest to this thesis. Studies were only included if the authors explicitly stated that they were carrying out a process evaluation, and it is likely that some studies of interest do not. The field of process evaluation, while under developed in relation to psychological interventions, may be better developed in areas such as occupational psychology. For example, a systematic review of studies focusing on individual or organisational level workplace stress management identified 84 studies which met inclusion criteria, although the authors concluded that fewer than half the studies presented any findings linking process evaluation and outcome evaluation, suggesting that incomplete reporting of process evaluations to a replicable level is a widespread problem (Murta, Sanderson, & Oldenburg, 2007).

Further limitations include a lack of detailed methodological steps, which would allow the scoping study and development of the framework to be replicated. There are no clear standardised methods for conducting a scoping study, which leaves methods open to researcher interpretation. The data from a scoping study has to be interpreted without an assessment of quality as would occur in a systematic review.

A strength of this study is that the framework was developed based on theoretical constructs, which can be translated into research questions. The role of theory is

crucial in enhancing explanatory power and predictive capability (Green, 2000). These theoretical concepts were used to underpin a checklist which can be used in a pragmatic way, in addition to the CONSORT statement for the design and conduct of RCTs and which has potential for other applications beyond the RCT, such as application to non-randomised studies, interventions which are already in routine use and quality improvement studies. These potential applications are discussed further in Chapter 9.

Summary and Conclusions

The concept of process evaluation originated in the 1980's in the community health intervention context. Psychological interventions are also type of complex intervention. Its methodological developments have been haphazard and although several attempts have been made to increase the awareness of the concept of process evaluation, it remains a poorly developed field. In more recent years, there have been attempts to describe the concept more fully, such as by the MRC, although the guidance remains theoretical.

Existing process evaluation frameworks, although representing important advancement of the field, are limited in their definition and depth of clarification of process evaluation components, with significant overlap, a lack of clear guidance for researchers wishing to conduct a process evaluation, including potential methodologies, and failure to account for the complexity of interventions due to reliance too heavily on either quantitative or qualitative measurement.

Derived from scoping the literature, twelve components of process evaluation are proposed. This is based on the themes that continuously emerge from theoretical discussions in the literature and should therefore be studied when testing a new, complex, psychological intervention. These components include *Formative Evaluation; Acceptability and Social Validity; Recruitment; Dose Delivered; Dose Received; Programme Implementation/Fidelity; Contamination; Provider Experience; Participant Experience; Context; Barriers and Facilitators; and*

Adoption. A range of (not exclusive) potential methodologies that can be used to study each component and a checklist for researchers is provided.

The next chapter will review the literature on process evaluations used to evaluate RCTs of psychological interventions designed to improve outcome in T2D.

Chapter 4: Literature Review

Chapter Summary

Chapter 3 outlined the purpose and importance of process evaluations of psychological interventions. The history of the field was described, including frameworks designed to aid researchers conducting process evaluations. A new framework was outlined, comprised of 12 processes that could be evaluated to understand the mechanisms of action of a psychological intervention. Quantitative and qualitative methods that could be used to measure the processes were described.

This chapter reviews RCTs of psychological interventions in T2D, describing the processes measured and the methods used to evaluate them. The process evaluation components identified and synthesised as a framework in Chapter 3 are used to summarise the literature.

Aims

1. To identify all studies reporting a process evaluation of an RCT of a psychological intervention to improve glycaemic control and other biomedical outcomes in T2D
2. To identify and describe the process evaluation components studied
3. To identify and describe the methods used to conduct the process evaluations.
4. To synthesise the range of process evaluation components and methods in order to identify any common or recurrent processes and methods.
5. To identify gaps in conducting process evaluation of psychological interventions using the framework proposed in Chapter 3.

Methods

Studies were identified in two phases, outlined in detail below. Phase 1 identified RCTs published 1966 – 2003. Phase 2 identified RCTs published 2003 -2016. All RCTs identified from both reviews are included in this review.

Phase 1: Studies were identified from a previously published systematic review and meta-analysis of RCTs of psychological interventions to improve glycaemic control in T2D originally led by my supervisors (Ismail et al., 2004). This work represented an important advance on previous systematic reviews in the area, which did not fully distinguish between: educational and psychological interventions; T1D and T2D; or randomised and non-randomised trials (Brown, 1992; Griffin, Kinmonth, Skinner, & Kelly, 1999; Meca, Rodriguez, & Alcazar, 1998; Norris, Engelgau, & Narayan, 2001; Snoek & Skinner, 2002).

The protocol for the study was peer reviewed and published in the Cochrane Database of Systematic Reviews (Cochrane Collaboration, 2017), and QUORUM (Quality of Reporting of Meta-analyses) guidelines were followed (David, Cook Deborah, Susan, Ingram, & Drummond, 1994) . Studies were identified via search of Medline, PsychINFO, EMBASE, and the Cochrane Central Register of Controlled Trials. The search strategy is provided in Appendix 1. Studies were eligible for inclusion if they were RCTs of a psychological intervention, for adult (18 years or older) patients with a diagnosis of T2D. Studies that did not explicitly label their method of intervention were included if they described one or more psychological techniques, which could be coded into one of the following categories: supportive or counseling therapy; CBT; brief psychodynamic psychotherapy or interpersonal psychotherapy. The criteria defining a psychological intervention were (i) reliance on communication using a therapeutic alliance between patient and therapist (ii) they were facilitated by a trained professional e.g. psychologist, psychotherapist, therapist in training or other trained professional supervised by a clinical psychologist or therapist (iii) the intervention was based on a psychological theory or model (iv) the intervention aimed to improve outcome in emotional, cognitive, and behavioural functioning, including adherence. Main outcome measures were long-term glycaemic control as measured by HbA1c. Secondary outcomes were body weight and psychological distress. Of the 25

RCTs identified, 12 were suitable for meta-analysis, which found that psychological therapies resulted in significantly better glycaemic control. This approximated to an absolute difference of 0.76% in HbA1c. However, ambiguous or vague descriptions of psychological interventions resulted in conclusions that the type of therapy that was most effective, and for which subgroup of patients, remained unclear.

Phase 2: Studies published were identified by the same methods as Phase 1. This review was conducted and led by the student's supervisors (KI and KW) and funded by an NIHR Health Technology Assessment grant from 01/01/2016 – 31/12/2017. Databases searched included CENTRAL, CINAHL, Embase, Medline, PsychINFO and Web of Science. RCTs were considered eligible for inclusion if they recruited participants with T2D and evaluated a psychological therapy designed to improve diabetes control. This work represents an important update to the previous review, because it used exactly the same methodology as the phase 1 review, which remains the most robust and comprehensive review of the impact of psychological therapies on biomedical outcomes in T2D.

Data Extraction

Studies included in the review for this thesis were defined as having conducted a process evaluation if the authors had either (i) stated they were conducting a process evaluation or process measures; (ii) carried out measures labeled with widely used process evaluation terminology e.g. 'dose received'; (iii) assessed a contextual component of the intervention such as participant or provider experience. However, as the construct of process evaluation was not widely understood or described until the past 5 years or so, we included studies that described a process measure even if it had not been defined as such, based on the assumption that the researchers had conducted the analysis 'in the spirit of process evaluation'. For example, a study may have measured fidelity of the intervention, but fidelity was not labelled as part of a process evaluation. In cases where methods or terminology were unclear, or process evaluation data were not reported, individual authors were contacted for clarification. An attempt to contact 56 authors was made, which yielded 5 responses (2 authors reported that no process evaluation was conducted, 2 authors reported no awareness

of process evaluation and 1 author responded with additional contact details, which did not yield a response). Trials were excluded if the article was not published in English.

Papers were searched for mentions of process evaluation or process evaluation measures which were conducted parallel to the RCT. Process evaluation papers were located by searching relevant online databases. If the authors had assessed a contextual component of the intervention such as participant or provider experience but not explicitly stated this was part of a process evaluation, searches of relevant online databases were conducted for the authors in question.

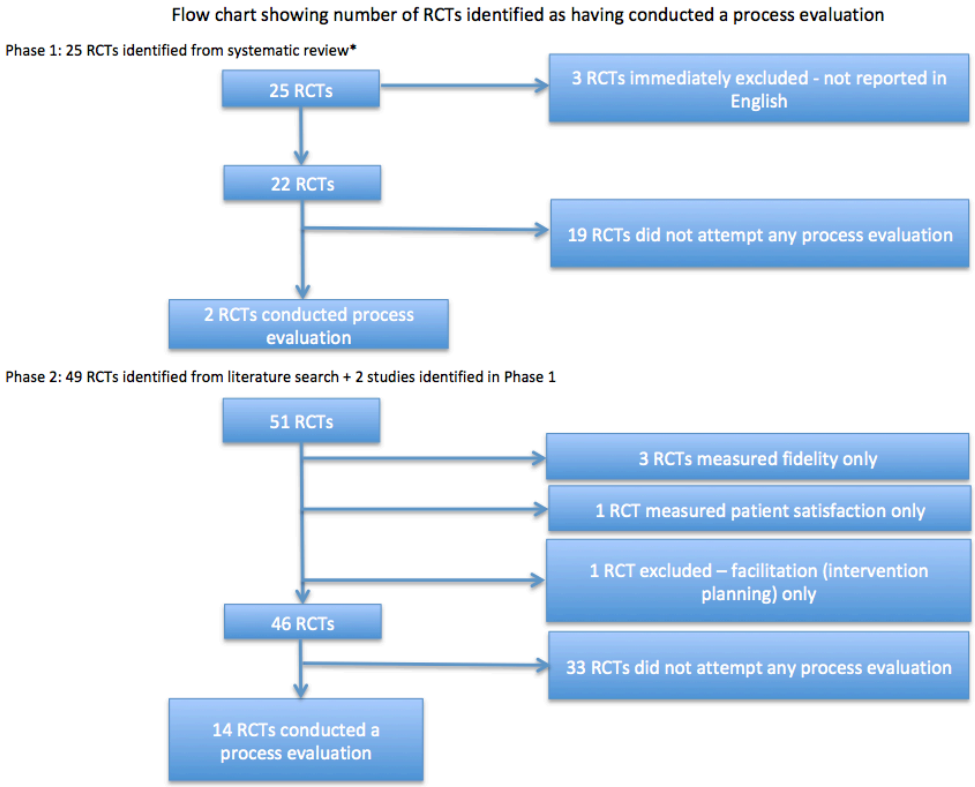
Results

Seventy-three RCTs were identified. Three were immediately excluded, as they were not reported in English, leaving 70 RCTs eligible for final review. Twenty-one RCTs were identified in Phase 1 and 49 RCTs in Phase 2. The number of studies that did and did not carry out process evaluations is detailed in the flow chart (Figure 4.1). The aims and extent of process evaluations conducted, if any, are summarised in Table 4.1. Of 70 trials identified, only 14 (20%) conducted any process evaluation (Adolfsson, Walker-Engström, Smide, & Wikblad, 2007; Blackberry et al., 2013; Campbell et al., 1996; Gabbay et al., 2013; Goode, Winkler, Reeves, & Eakin, 2015; Hill-Briggs et al., 2011; Jansink et al., 2013; Keogh et al., 2011; McKay, King, Eakin, Seeley, & Glasgow, 2001; Melkus et al., 2010; Moriyama et al., 2009; Pibernik-Okanovic, Begic, Ajdukovic, Andrijasevic, & Metelko, 2009; Waker, 2012; West, DiLillo, Bursac, Gore, & Greene, 2007). The components of process evaluation studied and the methods used are summarised in Tables 4.2 and 4.3 respectively. In 8 studies (61.5%) process evaluations were reported as part of the main RCT paper or thesis (Campbell et al., 1996; Hill-Briggs et al., 2011; Keogh et al., 2011; McKay et al., 2001; Melkus et al., 2010; Moriyama et al., 2009; Waker, 2012; West et al., 2007). The results of 2 process evaluations (16%) remain unpublished and therefore are not reported and 4 studies (29%) published process evaluation data as parallel studies (one of those published data as 2 separate papers) (Adolfsson et al., 2007; Jansink et al., 2013; Pibernik-Okanovic et al., 2009) (Adolfsson, Starrin, Smide, &

Wikblad, 2008; Adolfsson et al., 2007; Blackberry et al., 2013; Dellasega, Añel-Tiangco, & Gabbay, 2012; Furler et al., 2008; Gabbay et al., 2013; Goode et al., 2015; Walker et al., 2011).

Just 2 studies (Blackberry et al., 2013; Keogh et al., 2011) explicitly stated that the authors had conducted a process evaluation, while 3 studies (Campbell et al., 1996; McKay et al., 2001; West et al., 2007) reported 'process measures'. The remaining 9 studies were included as they studied intervention dose, provider or patient contextual processes.

Figure 4.1: Flow Chart Showing Studies Identified as Carrying out a Process Evaluation



*Phase 1 data obtained from Ismail et al 2004 (Ismail, Winkley K Fau - Rabe-Hesketh, & Rabe-Hesketh)

Table 4.1: Process Evaluations of Randomised Controlled Trials of Psychological Interventions to Improve Glycaemic Outcome in Patients with Type 2 Diabetes. Phase 1 (1966-2003) and phase 2 (2003-2016)

Authors, year, country, reference	Authors, year, country, reference of PE papers	Primary Outcome measures	Model and duration of psychological therapy in intervention group versus control group	Standardised effect size (95% CI) for change in HbA1c	Components of PE conducted	Methods used to conduct PE
Rabkin et al, 1983, Canada (Rabkin, Boyko, Wilson, & Streja, 1983)	Not reported.	HbA1c; skin fold thickness; weight loss at 6 and 12 weeks follow up.	Group CBT versus individual counselling (6-9 sessions) for 6 weeks.	1.10 (0.43 to 1.77)	Not reported.	Not reported.
Wing et al, 1985, USA (Wing, Epstein, Nowalk, Koeske, & Hagg, 1985)	Not reported.	HbA1c; weight; BMI; BP; cholesterol at 2, 4, 10 and 16 months follow up.	Group CBT for 16 sessions over 16 weeks, versus standard care.	0.25 (-0.36 to 0.84)	Not reported.	Not reported.
Hartwell et al, 1986, USA (Hartwell, Kaplan, & Wallace, 1986)	Not reported.	HbA1c; weight; lipids; body fat at 3 months follow up; and all of the above plus graded exercise test at 6 months follow up.	Weekly group CBT for 10 weeks, versus education only control group.	Authors report data as text*	Not reported.	Not reported.
White et al 1986, USA (White, Carnahan, Nugent, Iwaoka, & Dodson, 1986)	Not reported.	HbA1c, weight at 3 and 6 months follow up.	Group CBT for 6 months (10 sessions), versus advice-education control.	Authors report data as text*	Not reported.	Not reported.

Table 4.1 continued						
Heitzmann et al 1987, USA (Heitzmann, Kaplan, Wilson, & Sandler, 1987)	Not reported.	HbA1c; weight; body fat at 18 months follow up.	Group and individual CBT for 7 weekly sessions versus education only control group.	Authors report data as text*	Not reported.	Not reported.
Campbell et al 1990, Australia (Campbell et al., 1990)	Not reported.	Dietary compliance and fasting glucose at 1 month, 3 months and 6 months follow up.	Group counseling for 11 weeks (22 hours, staggered) versus standard care.	0.19 (-0.32 to 0.69)	Not reported.	Not reported.
Wing et al, 1991, USA (Wing, Marcus, Epstein, & Jawad, 1991)	Not reported.	HbA1c; fasting glucose; weight; BMI at week 24, 28, 40 and 72 week follow up.	Couple therapy (CBT) for 20 sessions, versus treatment alone.	0.45 (-0.16 to 1.05)	Not reported.	Not reported.
D'Eramo-Melkus et al, 1992, USA (D'Eramo-Melkus, Wylie-Rosett, & Hagan, 1992)	Not reported.	HbA1c; fasting glucose; weight at 3 and 6 months follow up.	Group education weight reductions intervention plus counselling (13 sessions) or education and weight reduction intervention alone (12 sessions) versus standard care.	-0.87 (-1.57 to -0.16)	Not reported.	Not reported.

Table 4.1 continued						
Boehm et al 1993, USA (Boehmk, Schlenk, Raleigh, & Ronis, 1993)	Not reported.	HbA1c; weight pre and post treatment.	Individual CBT in three groups focusing on medication adherence, behavioural strategies or behavioural strategies plus instruction, versus attention control. Treatment period average = 12.8 months, no. sessions unspecified.	- 0·68 (-1·33 to -0·03)	Not reported.	Not reported.
Lane et al 1993, USA (Lane, McCaskill, Ross, Feinglos, & Surwit, 1993)	Not reported.	HbA1c, Ghb levels; glucose tolerance at 3, 4, 5, and 6 months follow up.	Biofeedback assisted relaxation training weekly for 12 months, versus education only control group.	-0.33 (-0.97 to 0.31)	Not reported.	Not reported.
Campbell et al 1996, Australia (Campbell et al., 1996)	Not published separately. Results reported in RCT paper.	HbA1c; BMI; lipids; BP at 3, 6 and 12 months.	Group education, individual education, individual CBT or minimal intervention for 12 months (3 initial sessions followed by additional sessions as needed).	-0.59 (-1.16 to -0.01)	Dose delivered; dose received	Checklist of session duration; audiotaped sample of sessions (quantitative ratings)
Aikens et al, 1997, USA (Aikens et al., 1997)	Not reported.	HbA1c; glucose tolerance at weeks 1, 9 and 16.	Group CBT for 6 sessions over 8 weeks, versus usual care control group.	0.40 (-0.44 to 1.25)	Not reported.	Not reported.

Table 4.1 continued						
Henry et al, 1997, Australia (Henry, Wilson, Bruce, Chisholm, & Rawling, 1997)	Not reported.	HbA1c; fasting glucose; stress; anxiety; depression pre and post treatment.	Group CBT for 6 sessions over 6 weeks, versus usual care control group.	-0.43 (-1.34 to 0.48)	Not reported.	Not reported.
Jablon et al, 1997, USA (Jablon, Naliboff, Gilmore, & Rosenthal, 1997)	Not reported.	Glucose tolerance; fructosamine; HbA1c; stress via EMG and EDR pre and post treatment.	Stress reduction training for 4 weekly sessions versus usual care control group.	0.09 (-0.79 to 0.96)	Not reported.	Not reported.
Smith et al, 1997, USA (Smith, Heckemeyer, Kratt, & Mason, 1997)	Not reported.	BMI; fasting glucose; treatment adherence at baseline and post treatment (4 months).	Weight control counselling plus MI versus standard weight control counselling for 16 sessions over 4 months.	-0.34 (-1.36 to 0.68)	Not reported.	Not reported.
Lustman et al 1998, USA (Lustman et al., 1998)	Not reported.	HbA1c; depression post treatment and at 6 month follow up.	Group CBT and education biweekly for 10 weeks, versus education only control group.	-0.68 (-1.33 to -0.03)	Not reported.	Not reported.
Ridgeway et al, 1999, USA (Ridgeway et al., 1999)	Not reported.	HbA1c; fasting glucose; weight; lipids at 3, 6 and 12 months follow up.	Monthly group CBT and education for 6 months versus usual care control group.	-0.45 (-1.10 to 0.19)	Not reported.	Not reported.

Table 4.1 continued						
McKay et al 2001, USA (McKay et al., 2001)	Not published separately. Results reported in RCT paper.	HbA1c, physical activity; depression at 8-week follow up.	Individual CBT for 8 weeks (gradual online programme) versus information-only control group.	-0.35 (-0.83 to 0.13)	Dose delivered; participant experience	Tracking website usage; questionnaire with structured and unstructured components
Kenardy et al 2002, Australia (Kenardy, Mensch, Bowen, Green, & Walton, 2002)	Not reported.	HbA1c, disordered eating; psychological wellbeing post treatment and at 12 week follow up.	Weekly group CBT for 10 weeks versus weekly Non Prescriptive Therapy.	0.07 (-0.63 to 0.76)	Not reported.	Not reported.
Surwit et al 2002, USA (Surwit et al., 2002)	Not reported.	HbA1c at 2, 4, 6 and 12 months follow up.	Group CBT and education for 5 sessions over 2 months versus education only.	Authors report data as text*	Not reported.	Not reported.
Tsujiuchi et al 2002, Japan (Tsujiuchi et al., 2002)	Not reported.	HbA1c; fasting glucose; lipids; BP; BMI at pre and post treatment.	Group relaxation/CBT weekly for 4 months versus usual care control.	-0.47 (-1.27 to 0.33)	Not reported.	Not reported.
Clark et al, 2004, UK (Clark et al., 2004) (Studies from this point forward were identified in Phase 2)	Not reported.	HbA1c; physical activity; BMI; dietary behaviour; self-care activities at 3 and 12 months follow up.	Individual MI (4 in person sessions plus 3 follow up calls) over 7 weeks.	-0.06 (-0.45 to 0.33)	Not reported.	Not reported.

Table 4.1 continued						
Keeratiyutawong et al, 2006, Thailand (Keeratiyutawong, Hanucharurnkul, Melkus, Panpakdee, & Vorapongsathorn, 2006)	Not reported.	HbA1c at 3 and 6 months follow up.	Group CBT and education for 5 hours over 5 months versus education only control group.	-0.35 (-0.77 to 0.07)	Not reported.	Not reported.
Adolfsson et al. 2007, Sweden (Adolfsson et al., 2007)	Adolfsson et al. 2008, Sweden (Adolfsson et al., 2008)	HbA1c; weight; BMI at 8 week follow up.	Empowerment group education for 5 sessions over 7 months, versus usual care.	Authors report data as text*	Dose delivered; patient experience.	Session records; Patient interviews.
West et al 2007, USA (West et al., 2007)	Not published separately. Published in main RCT paper.	HbA1c; weight; BMI at 6, 12 and 18 months follow up.	Behavioural weight control program for 18 months with group MI over 5 sessions, versus attention control.	0.13 (-0.14 to 0.39)	Dose delivered; fidelity	Session records; Ratings of audiotaped sessions using MITI
French et al, 2008, UK (French et al., 2008)	Not reported.	HbA1c, well-being, illness and medication beliefs, beliefs about blood glucose self-monitoring at 3, 6, 9 and 12 months.	Online access to an 8 week personalized goal setting intervention versus information only control group.	0.06 (-0.21-0.34)	Not reported.	Not reported.
Moriyama et al, 2009, Japan (Moriyama et al., 2009)	Not published separately. Reported in main RCT paper.	HbA1c, physiological measures associated with risk factors at 3, 6, 9 and 12 months follow up.	Self-management education over 12 months (monthly sessions) versus usual care control group.	Authors report data as text*	Dose delivered; participant experience	Session records; structured questionnaire; open ended questionnaire

Table 4.1 continued						
Pibernik-Okanovic et al, 2009, Croatia (Pibernik-Okanovic et al., 2009)	Not published separately. Results unpublished.	HbA1c, depressive symptoms at 6 and 12 months follow up.	Group (4 sessions) and individual (2 monthly telephone calls) psycho-educational intervention for 12 months versus usual care control group.	Authors report data as text*	Dose delivered; participant experience	Session records; patient interviews
Sacco et al 2009, USA (Sacco, Malone, Morrison, Friedman, & Wells, 2009)	Not reported.	HbA1c; adherence (diet, glucose testing, medication); BMI; diabetes symptoms; depressive symptoms pre and post intervention.	Psycho-educational telephone coaching (weekly for 3 months then bi-weekly for 3 months) versus usual care control group.	-0.17 (-0.67 to 0.32)	Not reported.	Not reported.
Stuckey et al 2009, USA (Stuckey et al., 2009)	Not reported.	HbA1c; lipids; BP, cholesterol at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, then 6 monthly.	Self-management education and MI for 2 years (2 weeks, 6 weeks, 3 months, 6 months, 12 months, then 6 monthly) versus usual care control.	Authors report data as text*	Not reported.	Not reported.
De Greef et al, 2010, Belgium (De Greef, Deforche, Tudor-Locke, & De Bourdeaudhuij, 2010)	Not reported.	HbA1c, physical activity at 12 weeks and 1 year follow up.	Cognitive behavioural intervention using mixed methods for 12 weeks (5 sessions) plus 1 booster session, versus usual care control group.	0.33 (-0.29 to 0.95)	Not reported.	Not reported.

Table 4.1 continued						
D'Eramo Melkus et al, 2010, USA (Melkus et al., 2010)	Not published separately. Published in main RCT paper.	HbA1c; cardiovascular risk profile at 3, 6, 9, 12 and 24 months follow up.	Cognitive behavioural diabetes self-management and coping skills training for 12 months (11 weekly group sessions) versus usual care control group.	0.11 (-0.27 to 0.48)	Dose delivered; fidelity; barriers and facilitators	Session records; Trainer observation of CBT delivery; open-ended questionnaire
Heisler et al, 2010, USA (Heisler, Vijan, Makki, & Piette, 2010)	Not reported.	HbA1c at 6 month follow up.	Weekly reciprocal peer support for 6 months versus enhanced usual care.	Authors report data as text*	Not reported.	Not reported.
Pourisharif et al 2010, Iran (Pourisharif et al., 2010)	Not reported.	BMI and HbA1c 9 weeks post intervention.	Cognitive behavioural group training and MI for 4 sessions versus no treatment control group.	Authors report data as text*	Not reported.	Not reported.
Shi et al, 2010, China (Shi, Ostwald, & Wang, 2010)	Not reported.	HbA1c and self-efficacy at 1 and 4 months follow up.	Weekly education and self-efficacy promotion for 4 weeks versus usual care control group.	Authors report data as text*	Not reported.	Not reported.
Wolever et al, 2010, USA (Wolever et al., 2010)	Not reported.	Exercise and medication adherence; psychological functioning; HbA1c at post treatment follow up.	Integrative Health Coaching for 14 sessions over 6 months versus usual care control group.	0.32 (-0.85 to 0.21)	Not reported.	Not reported.

Table 4.1 continued						
Osborn et al, 2010, USA (Osborn et al., 2010)	Not reported.	Food label reading; dietary adherence; physical activity; HbA1c immediately post intervention and 3 months post intervention.	MI for 3 90-minute sessions versus usual care control group.	-0.14 (-0.47 to 0.19)	Not reported.	Not reported.
Castelnuovo et al 2011, Italy (Castelnuovo et al., 2011)	Not reported.	HbA1c, weight at discharge from hospital then 3, 6 and 12 months follow up.	Nutritional counselling, CBT and physical activity training for 12 months (1 month inpatient programme followed by internet based resources) versus usual care control group.	Authors report data as text*	Not reported.	Not reported.
De Greef et al, 2011, Belgium (De Greef, Deforche, Tudor-Locke, & De Bourdeaudhuij, 2011)	Not reported.	HBA1c, physical activity at 12 weeks follow up.	Multiple behaviour change techniques including CBT and MI for 12 weeks (3 x 90 minute sessions). Delivered individually or in groups versus no treatment control group.	-0.10 (-0.68 to 0.49)	Not reported.	Not reported.

Table 4.1 continued						
Hill-Briggs et al, 2011, USA (Hill-Briggs et al., 2011)	Not published separately. Results reported in main RCT paper.	HbA1c; BP; cholesterol post intervention and 3 months post intervention follow up.	Intensive education and problem solving self-management training (9 sessions) or condensed problem solving and education training (2 sessions) versus no treatment control group.	Authors report data as text*	Dose delivered; fidelity; participant experience (patient satisfaction and acceptability)	Session records; Audiotaped sessions (review method unspecified); structured questionnaire
Keogh et al 2011, Ireland (Keogh et al., 2011)	Keogh et al 2007, Ireland (detailed in protocol paper). Partial results reported in main RCT paper (reasons for dose not receiving intervention)	HbA1c; illness perceptions; psychological wellbeing at 6 month follow up.	MI for 3 weekly sessions versus usual care control group.	-0.15 (-0.51 to 0.20)	Dose delivered and received; fidelity; participant experience	Session records; audiotapes sample independently rated; qualitative & quantitative analysis of tapes using checklists; open-ended questionnaire; focus group; field notes
Lamers et al 2011, Netherlands (Lamers, Jonkers Cc Fau - Bosma, Bosma H Fau - Knottnerus, Knottnerus Ja Fau - van Eijk, & van Eijk)	Not reported.	HbA1c (collected from GP records); disease related quality of life at 1 week, 3 and 9 months post-intervention.	CBT and self-management intervention for an average of four sessions versus usual care control group.	-0.61 (-1.09 to -0.13)	Not reported.	Not reported.

Table 4.1 continued						
Piette et al, 2011, USA (Piette et al., 2011)	Not reported.	HbA1c at 12 month follow up.	Telephone delivered weekly CBT for 12 weeks, plus 9 booster sessions (12 months in total), versus enhanced usual care.	0.12 (-0.11 to 0.35)	Not reported.	Not reported.
Welch et al 2011, USA (Welch et al., 2011)	Not reported.	HbA1c at 3 and 6 month follow up.	MI and diabetes self-management education for 4 sessions over 6 months versus diabetes self-management education alone.	.023 (-0.13 to 0.59)	Not reported.	Not reported.
García-Huidobro et al 2011, Chile (García-Huidobro, Bittner, Brahm, & Puschel, 2011)	Not reported.	HbA1c at 6 and 12 month follow up.	Family and individual counselling (5 sessions) for 12 months, versus usual care.	0.38 (0.07 to 0.69)	Not reported.	Not reported.
Chen et al 2012, Taiwan (Chen, Creedy, Lin, & Wollin, 2012)	Not reported.	HbA1c at 3 month follow up.	MI for 1 hour, versus weekly hospital based education sessions.	-0.38 (-0.65 to -0.11)	Not reported.	Not reported.

Table 4.1 continued						
Hartmann et al, 2012, Germany (Hartmann et al., 2012)	Not reported.	HbA1c, progression of nephropathy post treatment and once a year for 5 years.	Mindfulness based stress reduction intervention once a week for 8 weeks, with a booster session after 6 months, versus usual care.	-0.36 (-0.74 to 0.01)	Not reported.	Not reported.
Penckofer et al 2012, USA (Penckofer et al., 2012)	Not reported.	HbA1c, depression at 3 and 6 months follow up.	CBT weekly for 8 weeks plus 2 booster sessions, versus no treatment control group.	-0.63 (-1.10 to -0.16)	Not reported.	Not reported.
Waker et al 2012, USA (thesis) (Waker, 2012)	Not published separately. Published as part of thesis.	HbA1c and self management behaviours post treatment and 3 month follow up.	MI for two 60 minute sessions versus usual care control group.	0.19 (-0.13 to 0.51)	Dose delivered; fidelity; participant experience (acceptability)	Session data; Rating of audiotaped sessions using MITI; structured and open-ended questionnaire
Blackberry et al 2013, Australia (Blackberry et al., 2013)	Furler et al, 2008, Australia	HbA1c at 18 months.	Educational and empowerment based 'telephone coaching' for 15 months (9 sessions), versus usual care control.	Authors report data as text*	Dose delivered; pre-trial formative evaluation	Session data; focus groups exploring the role of health professionals in encouraging self-management.
	Walker et al, 2011, Australia (Walker et al., 2011)	HbA1c at 18 months.	Educational and empowerment based 'telephone coaching' for 15 months (9 sessions), versus usual care control.		Dose delivered and received; fidelity; participant experience; nurse experience; GP experience	Random sample of sessions recorded and analysed qualitatively; research staff field notes; interviews and focus groups with patients, nurses and GPs.

Table 4.1 continued						
Gabbay et al 2013, USA (Gabbay et al., 2013)	Dellasega et al, 2012, USA (Dellasega et al., 2012)	HbA1c at 2 year follow up.	MI for two years (8 sessions), versus usual care control group.	Authors report data as text*	Dose delivered; fidelity; participant experience (acceptability).	Session data; audiotaped sessions rated using BECCI and other reviewer; focus groups with patients to determine acceptability of MI.
Jansink et al, 2013, The Netherlands (Jansink et al., 2013)	Not published separately. Results unpublished.	HbA1c; diet; physical activity at 14 months follow up.	Education, lifestyle counselling and MI for 14 months versus usual care control group.	-0.25 (-0.45 to -0.05)	Dose delivered; nurses' experiences; barriers and facilitators.	Session data; follow up meeting/focus group post intervention.
Mohamed et al 2013, Qatar (Mohamed, Al-Lenjawi, Amuna, Zotor, & Elmahdi, 2013)	Not reported.	HbA1C; fasting glucose; lipid profile; albumin/creatinine ratio; BMI and blood pressure at 12 month follow up.	Education and counseling for 4 sessions over 12 months versus education alone group.	Authors report data as text*	Not reported.	Not reported.
Safren et al 2013, USA (Safren et al., 2013)	Not reported.	HbA1c, medication adherence; depression at 12 month follow up.	CBT for 12 months (9-12 sessions) versus enhanced usual care group.	-0.55 (-0.98 to -0.12)	Not reported.	Not reported.

Table 4.1 continued						
Trief et al, 2013, USA (Trief et al., 2013)	Not reported.	Medication adherence; HbA1c at yearly follow up for 5 years.	Education and goal setting by video phone, every 5-6 weeks for 5 years, versus usual care control group.	Authors report data as text*	Not reported.	Not reported.
Welschen 2013, The Netherlands (Welschen et al., 2013)	Not reported.	HbA1c, CHD risk at 6 and 12 months follow up.	CBT for 6 sessions over 6 months versus usual care control group.	-0.10 (-0.42 to 0.22)	Not reported.	Not reported.
Plotnikoff et al 2013, Australia (Plotnikoff et al., 2013)	Not reported.	Physical activity; HbA1c at 6, 12 and 18 months.	Education and telephone counseling every 3 months for 12 months versus enhanced education versus education alone control group.	0.05 (-0.23 to 0.34)	Not reported.	Not reported.
Chao et al, 2014, China (Chao et al., 2014)	Not reported.	Fasting glucose at 18 months follow up.	Health management programme with psychological and educational components once a month for 18 months versus usual care control group.	Authors report data as text*	Not reported.	Not reported.
Li et al, 2014, China (Li, Li, Shi, & Gao, 2014)	Not reported.	HbA1c at 6 months follow up.	Monthly MI for 7 months versus education alone control group.	-0.16 (-0.55 to 0.23)	Not reported.	Not reported.

Table 4.1 continued						
Lynch et al 2014, USA (Lynch, 2014)	Not reported.	HbA1c, weight at 6 months follow up.	Education, behavioural skills training and social support for 18 sessions plus weekly phone calls, versus education only control group.	Authors report data as text*	Not reported.	Not reported.
Eakin et al, 2014, Australia (Eakin et al., 2014)	Goode et al, 2015 (Goode et al., 2015)	Weight; physical activity; HbA1c at 18 and 24 months.	MI for 18 months (maximum of 27 phone calls) versus usual care control group.	-0.03 (-0.27 to 0.20)	Dose delivered, dose received.	Number of telephone counselling calls completed.
Rothschild et al 2014, USA (Rothschild et al., 2014)	Not reported.	HbA1c at 12 and 24 months follow up.	Education and self-management training for 2 years (36 visits) versus education only control group.	Authors report data as text*	Not reported.	Not reported.
Chlebowy et al 2014, USA (Chlebowy et al., 2014)	Not reported.	HbA1c; random serum glucose; BMI at 3 months follow up.	MI for 3 months (6 sessions) versus usual care control group.	-0.58 (-1.10 to -0.07)	Not reported.	Not reported.
Young et al, 2014, USA (Young et al., 2014)	Not reported.	HbA1c, self-efficacy; physical and mental QoL; satisfaction with diabetes care at 9 months follow up.	MI via video phone for 5 sessions over 9 months versus usual care control group.	Authors report data as text*	Not reported.	Not reported.

Table 4.1 continued						
Chen et al, 2015, Taiwan (Chen, Wang, Lin, Hsu, & Chen, 2015)	Not reported.	HbA1c post treatment and 3 months post treatment follow up.	Empowerment programme for 3 months (monthly visits with 3 follow up phone calls per month) versus usual care control group.	-0.38 (-0.65 to -0.11)	Not reported.	Not reported.
Pladevall et al 2015, USA (Pladevall, Divine, Wells, Resnicow, & Williams, 2015)	Not reported.	HbA1c; cholesterol at 18 months follow up.	Education and MI for 18 months versus adherence information group or usual care control group.	-0.09 (-0.21 to 0.03)	Not reported.	Not reported.
Browning et al, 2016, China (Browning et al., 2016)	Not reported.	HbA1c at 12 months follow up.	MI for 12 months 8 face-to-face and 8 telephone sessions) versus usual care control group.	-0.06 (-0.37 to 0.25)	Not reported.	Not reported.
Huang et al, 2016, Taiwan (Huang et al., 2016)	Not reported.	HbA1c; mental and physical QoL; BMI and depression at post intervention and 3 months post intervention follow up.	Mi and CBT for12 sessions over 3 months versus usual care control group.	-0.68 (-1.20 to -0.17)	Not reported.	Not reported.

Table 4.1 continued						
Kasteleyn et al, 2016, The Netherlands (Kasteleyn, Vos, Rijken, Schellevis, & Rutten, 2016)	Not reported.	HbA1c, diabetes related distress at 5 months follow up.	Intervention based on Social Cognitive Theory (Bandura, 2011) and Leventhal's Common Sense Model (Leventhal et al., 2003) for 3 sessions over 2 months versus an attention control group.	-0.06 (-0.37 to 0.25)	Not reported.	Not reported.
Kim et al 2016, USA (Kim et al., 2016)	Not reported.	HbA1c; cholesterol; lipids at 12 months follow up.	12 sessions of group education and self-management training for 12 months plus 4 counselling sessions versus no treatment control group.	-3.0 (-3.40 to -2.60)	Not reported.	Not reported.

BMI = Body Mass Index; BP = Blood Pressure; CBT = Cognitive Behavioural Therapy; CHD = Coronary Heart Disease; EDR = Electrodermal Response; EMG = Electromyogram; MI = Motivational Interviewing; PE = Process Evaluation; QoL = Quality of Life.

* Data insufficient to pool into meta-analysis.

Components of Process Evaluation Reported

The components of process evaluation studied by the RCTs selected for review are summarised in Table 4.2.

Just 1 study (Blackberry et al., 2013) conducted a *Formative Process Evaluation* prior to the main RCT. Blackberry et al conducted a prospective, cluster randomised RCT in Australia to evaluate the effectiveness of goal focused telephone coaching delivered by practice nurses in improving glycaemic control in people with T2D (n=473). The unit of cluster was the patient's GP surgery. Nurses received 2 days training in a telephone coaching programme, delivering 8 telephone sessions and 1 face to face session per patient. At 18 month post-baseline follow up, no significant difference was observed between control and intervention groups. Prior to the main study, the authors conducted a *Formative Process Evaluation* underpinned by a theoretical framework, using focus groups to explore the role of health professionals in encouraging self-management. They concluded that self-management support should be part of an ongoing and established relationship between health professional and patient, although this approach should be individually tailored (Furler et al., 2008). However, they did not report how this information informed the future design of their RCT. This was the most comprehensive process evaluation of the studies reviewed, assessing 6 of the potential 12 process evaluation components outlined in Chapter 3. The full process evaluation comprised the pre-trial focus groups exploring health professionals' views on self-management (*Formative Evaluation*); quantitative session data (*Dose Delivered*); a sample of sessions recorded and rated qualitatively; research staff field notes (*Dose Received, Fidelity*); interviews and focus groups (*Participant Experience, Provider Experience*). The process evaluation revealed the complexity of patients' diabetes management within their social contexts and revealed differing styles of intervention delivery among health providers (Walker et al., 2011). The analysis of audiotaped sessions enabled the authors to define two styles of consultation: 'treat to target' and 'personalized care', which correspond to directive and non-directive approaches. The data revealed how healthcare professionals vary in their approaches, which could be included as a variable in future analyses. The data provided important information about social context, which can be ignored within a

standard RCT. The authors concluded that further research is needed into 'the mechanisms of social context in the way people manage their health.' These findings were particularly important in light of the non-significant outcome.

Data on consultation style also emerged from the process evaluation of an RCT conducted by Adolfsson et al (Adolfsson, Smide, Gregeby, Fernström, & Wikblad, 2004) who tested the efficacy of nurse and physician delivered empowerment group education versus usual diabetes care in improving diabetes outcomes among 101 patients at 7 'primary care centres' in central Sweden. No significant differences were found on main outcome measures, although patients' confidence in diabetes knowledge was significantly higher than the control group at 12 months post baseline. The researchers conducted semi-structured interviews with patients after treatment to investigate *Participant Experience* and found that two different styles of communication emerged from the data. In the usual care group, relationships between patient and provider were 'vertical', meaning that the provider directed the conversation, giving patients instructions about diabetes management, which they were expected to follow. By contrast, the intervention group experienced 'horizontal' interactions, where patient and provider formulated a self-management plan via a collaborative process.

Campbell et al conducted a 4 arm RCT comparing the effects of a group education program (n=66), an individual education program (n=57), a behavioural program (n=59) and a minimal contact program (n=59) on T2D outcomes was conducted in Australia (Campbell et al., 1996). The four groups were not differentially effective on measures of HbA1c and BMI at 3, 6 and 12 months post-baseline. The authors used checklists of attendance sessions to measure *Dose Delivered* and audiotaped a sample of consultations to measure *Fidelity*, finding that patients adhered to intervention protocols. The process evaluation data suggest that the intervention was delivered according to protocol and the implication is that the results indicate a true failure of the intervention, rather than protocol deviation.

Eakin et al conducted a 2 arm RCT comparing a telephone delivered behavioural weight loss intervention targeting primary care T2D patients in Australia with usual care (n=78). The inter vention included goal setting, personalised feedback, strategies

for overcoming personal barriers and peer support. They observed a moderate improvement in physical activity levels in both arms but there were no significant between group differences on outcome measures. The authors used records of telephone sessions completed to assess *Dose delivered* and *Dose received* finding that call completion was significantly associated with weight loss but no other outcome variables (including physical activity level or HbA1c). Those with a previous diagnosis of depression or anxiety were also disproportionately represented in the 'low call completion' group. Mood disorders are often associated with suboptimal diabetes control (Lustman et al., 2000). This process evaluation data shows that in choosing not to screen out patients with previous diagnoses of depression and anxiety contributed to the low call completion rate and therefore the completion of the RCT according to protocol.

Waker conducted an RCT to test the efficacy of MI in improving HbA1c and self-management behaviours among 154 participants with T2D in Cincinnati, US (Waker, 2012). Patients were recruited from their GP surgery, with those in the intervention group receiving 2 usual care and 2 x 60-minute MI sessions (versus 2 usual care appointments in the control group). The hypothesis that participants receiving the MI intervention would demonstrate significant improvements in HbA1c and self-management behavioural outcomes was not supported. *Fidelity* was assessed using a random sample of audiotaped intervention sessions, rated using the MITI. The intervention was delivered according to protocol. These results show that the failure of the intervention is likely attributable to the intervention design, rather than protocol deviation. Intervention group participants also completed an acceptability questionnaire providing responses on a 7-point Likert scale, assessing *Participant Experience*. Participants rated the intervention as acceptable and helpful (mean 6.07 for acceptability and 5.23 for helpfulness). Participants also made suggestions for improvement, expressing the desire for more MI sessions, more frequent sessions and group sessions. Since participants were only offered 2 sessions of MI, these data suggest that increasing the amount of sessions may improve outcome.

D'Eramo Melkus et al tested the efficacy of a 10-week diabetes self-management and coping skills intervention versus usual education and diabetes care on physiological and psychosocial outcomes in 109 African American women with T2D in primary

care. Findings suggested that the combination of diabetes self-management and coping skills may lead to improvements in metabolic control. They observed significant improvements in HbA1c in both groups at 3 months, and these changes were sustained at 12 and 24 months follow up. The authors collected data on *Dose Delivered* and *Barriers and Facilitators* to participation in the study. The quantitative data revealed that participants who didn't attend sessions had lower levels of education and income and were less likely to be working. They also had poorer quality of life (QoL) in all domains. This data may be used to inform the design of future interventions, which could provide more intensive or individualised care for those who need it. Qualitative data focusing on *Barriers and Facilitators* established specific reasons for non-attendance, including stressful life events such as the death of a child or spouse (including 2 by murder), incarceration of a child and the onset of illness in a child. The qualitative data revealed the complexity of the social context from which this sample was drawn. They concluded that future interventions should be more comprehensive, addressing the physiological and psychosocial needs of patients in a setting that is convenient for them (Melkus et al., 2010).

McKay et al conducted an RCT comparing a physical activity intervention with an information only condition. Seventy-eight T2D patients recruited across the US and Canada were randomised to receive either an intervention comprising goal-setting and feedback, strategies to overcome barriers, access to an online 'personal coach' and peer group support, versus information only. No significant difference in activity levels was observed between the 2 groups. Process evaluation data including records of the amount of *Dose Delivered* showed a steep decline in the amount of sessions delivered over the 8 weeks of the trial, which may partly explain null findings. The authors also conducted a post-trial 'user satisfaction survey' to assess *Participant Experience*, finding that intervention participants reported greater satisfaction than those in the information only group. They reported that 88% of participants found the intervention helpful compared to 35% in the information only group (McKay et al., 2001). This data contradicts the behaviour of participants and highlights the need for more informative qualitative responses, which may reveal reasons behind non-attendance.

Pibernick-Okanovic et al conducted an RCT in Croatia, comparing a group and individual psycho-educational intervention delivered over 12 months, designed to reduce depressive symptoms, with diabetes care as usual. Fifty patients with mild to moderate depressive symptoms and T2D were randomly assigned to control or intervention groups. Intervention group participants received 4 psycho-educational sessions aimed at enabling self-management of depressive symptoms. They found statistically significant improvements in both depressive symptoms and HbA1c in both control and intervention conditions at 6 and 12 months post-baseline. However, no significant between group differences were observed. The authors concluded that the additional attention received by participants in their 'usual care' condition (participants also received depression screening and feedback) could explain the significant improvements in outcome observed within the group. The qualitative evaluation of *Participant Experience* of taking part in the RCT supported this hypothesis. Qualitative data showed that participants found the sense of being supported and cared for the most valuable aspect of participation. This was a common element to both experimental groups and therefore offers an explanation for the results (Pibernik-Okanovic et al., 2009). Qualitative data collected as part of a process evaluation allowed the researchers to support a hypothetical explanation.

The remaining 6 RCTs attempted partial process evaluation but methods were either insufficiently sensitive to capture data or data were not reported. For example, Hill-Briggs et al conducted an RCT of an education and problem solving self-management program delivered in both an intensive and condensed format, aimed at improving HbA1c and reducing cardiovascular risk factors among 56 African American men in Baltimore. They reported significant improvement in HbA1c at 3-month follow up. Patients completed satisfaction ratings post intervention, which showed they found it helpful and easy to understand. Participants in the intensive intervention group reported they learned more than those in the condensed group (Hill-Briggs et al., 2011). Although it useful to know that participants were happy with an intervention, the data tell us little beyond that, highlighting the need for deeper qualitative investigation as part of a process evaluation.

Similarly, Moriyama et al conducted an RCT of a self-management education intervention versus usual care, aimed at improving HbA1c and physiological

measures associated with cardiovascular risk factors at 12 month follow up. The intervention group (n = 42) received <30 min of monthly interviews in Hiroshima, Japan, based on the programme's textbook and biweekly telephone calls from a nurse educator. Significant improvements were observed in HbA1c and risk factor variables. Quantitative data from structured questionnaires revealed that participants felt the program to be valuable (95%). They also reported that the length of sessions was neither 'long nor short' (76.3% in the intervention group) which may indicate a central response bias. 100% of patients felt the program was 'necessary'. Open-ended questionnaire responses revealed that participants felt the program was 'easy to understand' and 'it was good to set individual goals and get proper advice' (Moriyama et al., 2009). These findings can be used to inform the design of future interventions, but would benefit from further qualitative exploration.

Gabbay et al conducted an RCT comparing the effect of MI over a 2-year period on diabetes self-management and HbA1c, versus usual care. A significant improvement in HbA1c was observed among the intervention group comprising 232 patients at 12 primary care clinics in Pennsylvania, US, but it was unclear if this was due to increased attention, increased provider interaction or improved knowledge from educational material. Fidelity of the intervention was monitored by review of audiotaped sessions by two MI experts. The results are not reported in detail but the authors state that interventionists were MI adherent (Gabbay et al., 2013). It would be interesting to see complete fidelity data in order to better understand the origin of treatment effects.

West et al conducted an RCT of an 18-month, group-based behavioral obesity treatment, with 217 overweight women randomised to individual sessions of MI or attention control as an adjunct to a weight control programme. Participants in the MI group lost significantly more weight at 6 and 18 months and had significantly lower HbA1c at 6 months although this improvement was not sustained at 18 months follow up. Attendance records and self-monitoring diaries were used to monitor intervention *Dose Delivered* and the authors reported that those in the MI group submitted significantly more self-monitoring diaries than those in the attention control group. Randomly selected audiotapes of recorded MI sessions were reviewed weekly by 2

clinical psychologists to assess *Fidelity* to MI. The results are not reported (West et al., 2007).

Keogh et al conducted an RCT to test the effectiveness of a psychological, family-based intervention aimed at improving outcome in patients with poorly controlled T2D (n=121) in a large suburban hospital in Ireland. Intervention group participants received 3 weekly sessions (2 45-minute sessions delivered at home, 1 15-minute telephone session) delivered by a health psychologist who received 16 hours of training in MI. The intervention group showed significant improvement in HbA1c at 6-month follow-up and also significant improvements in beliefs about diabetes, psychological wellbeing, diet, exercise, and family support. The authors measured *Dose Delivered* and *Fidelity* components of process evaluation, and report that the intervention was delivered according to protocol, although data are not presented (Keogh et al., 2011). In a protocol paper the authors state they will use focus groups and structured questionnaires to assess participant experience of the intervention but these data are not published (Keogh et al., 2007).

Jansink et al conducted a cluster RCT to test the effect of an education, lifestyle counselling and MI intervention on HbA1c, diet and physical activity levels. Patients (n=940) were recruited from 58 primary care practices in The Netherlands. No significant' effect on outcome variables compared with usual care was observed at 14 months follow up. Nurses were invited to participate in a focus group/follow up meeting post trial although participation was low (37%) and data are not reported (Jansink et al., 2013).

Table 4.2: Components of Process Evaluation Studied by Randomised Controlled Trials Identified for Review

	Formative Process Evaluation	Formative Acceptability and Social Validity	Recruitment	Dose Delivered	Dose Received	Fidelity	Contamination	Provider Experience	Participant Experience	Context	Barriers and Facilitators	Adoption
Campbell et al 1996, Australia (Campbell et al., 1996)				X	X	X						
McKay et al 2001, USA (McKay et al., 2001)				X					X			
Adolfsson et al. 2007, Sweden (Adolfsson et al., 2007)				X					X			
West et al 2007, USA (West et al., 2007)				X		X						
Moriyama et al, 2009, Japan (Moriyama et al., 2009)				X					X			
Pibernik-Okanovic et al, 2009, Croatia (Pibernik-Okanovic et al., 2009)				X					X			
D'Eramo Melkus et al, 2010, USA (Melkus et al., 2010)				X		X					X	
Hill-Briggs et al, 2011, USA (Hill-Briggs et al., 2011)				X		X			X			
Keogh et al 2011, Ireland (Keogh et al., 2011)				X	X	X			X			
Waker et al 2012, USA (thesis) (Waker, 2012)				X		X			X			
Blackberry et al 2013, Australia (Blackberry et al., 2013)	X	X		X	X	X		X	X			
Gabbay et al 2013, USA (Gabbay et al., 2013)				X		X			X			
Jansink et al, 2013, The Netherlands (Jansink et al., 2013)				X				X			X	

Selection and Combination of Methods

Table 4.3 summarises the methods used to conduct the process evaluations.

All studies collected quantitative process evaluation data. This is unsurprising, as the CONSORT statement requires researchers to collect data on the amount of intervention *Dose Delivered*. Ten studies collected additional quantitative data, with 5 obtaining quantitative ratings of audio recordings (Campbell et al., 1996; Gabbay et al., 2013; Keogh et al., 2011; Waker, 2012; West et al., 2007) and 5 using structured questionnaires (Hill-Briggs et al., 2011; Keogh et al., 2011; McKay et al., 2001; Moriyama et al., 2009; Waker, 2012). For example, West et al conducted an 18-month RCT testing the effectiveness of a group based behavioural obesity treatment using MI versus an attention control condition. Women in the intervention group had lost significantly more weight at 6 and 12-month follow up. Attendance records were used to track patient engagement with the intervention. Results showed that intervention group participants were significantly more engaged with the intervention during the intervention phase of the trial, after which time their attendance at follow up sessions was equal to those in the control group (West et al., 2007).

Nine studies (77%) collected some form of qualitative data, with 4 studies obtaining qualitative data from audiotaped recordings (Blackberry et al., 2013; Gabbay et al., 2013; Hill-Briggs et al., 2011; Keogh et al., 2011), 5 studies using open-ended questionnaires (Keogh et al., 2011; McKay et al., 2001; Melkus et al., 2010; Moriyama et al., 2009; Walker et al., 2011), 4 studies using interview methods (Adolfsson et al., 2007; Blackberry et al., 2013; Pibernik-Okanovic et al., 2009), 3 studies using focus groups (Blackberry et al., 2013; Gabbay et al., 2013; Jansink et al., 2013; McKay et al., 2001) and 3 studies using observational data (some studies employed more than one of these methods in combination) (Blackberry et al., 2013; Keogh et al., 2011; Melkus et al., 2010).

Discounting quantitative data collected as a requirement of CONSORT, only 5 studies collected both quantitative and qualitative data as part of their process evaluations (Gabbay et al., 2013; Keogh et al., 2011; McKay et al., 2001; Melkus et al., 2010;

Waker, 2012). The use of mixed methods is a core feature of process evaluation and this review suggests that this requirement is not consistently met.

Table 4.3: Summary of Methods Used to Conduct Process Evaluations.

	Intervention	**Quantitative Methods**	**Qualitative Methods**
Campbell et al, 1996, Australia (Campbell et al., 1996)	Individual CBT for 12 months, aimed at improving HbA1c and reducing cardiovascular risk factors.	Session attendance (*Dose Delivered*), including checklist of session duration.	Audiotaped sample of sessions, rated quantitatively (*Dose Received, Fidelity*).
McKay et al, 2001, USA (McKay et al., 2001)	Individual CBT for 8 weeks, aimed at increasing physical activity and reducing depressive symptoms.	Website usage data (*Dose Delivered*) and a questionnaire with structured and unstructured components, yielding quantitative and qualitative data (*Participant Experience*).	Questionnaire with structured and unstructured components, yielding quantitative and qualitative data (*Participant Experience*).
Adolfsson et al, 2007, Sweden (Adolfsson et al., 2007)	Empowerment group education for 7 months, aimed at reducing HbA1c and cardiovascular risk factors.	Session records (*Dose Delivered*).	Semi-structured interviews (*Participant Experience*).
West et al, 2007, USA (West et al., 2007)	Behavioural weight control program for 18 months, and individual and group MI for 12 months, aimed at reducing HbA1c and cardiovascular risk factors.	Session records (*Dose Delivered*) and quantitative data from ratings of audiotaped sessions (*Fidelity*).	None reported.
Moriyama et al, 2009, Japan (Moriyama et al., 2009)	Self-management education for 12 months aimed at improving HbA1c and physiological measures associated with risk factors.	Session records (*Dose Delivered*), quantitative data from structured questionnaire	Open-ended questionnaire (*Participant Experience*).
Pibernick-Okanovic etc al, 2009, Croatia (Pibernik-Okanovic et al., 2009)	Group and individual psycho-educational intervention for 12 months aimed at reducing depressive symptoms.	Session use data (*Dose Delivered*)	Patient interviews (*Participant Experience*).
D'Eramo Melkus et al, 2010, USA (D'Eramo-Melkus et al., 1992)	Cognitive behavioural diabetes self-management and coping skills training for 12 months aimed at improving HbA1c and cardiovascular risk profile.	Session use data (*Dose Delivered*), trainer observation of CBT delivery (*Fidelity*)	Open-ended questionnaires (*Barriers and Facilitators*).

Table 4.3 continued			
Hill-Briggs et al, 2011, USA (Hill-Briggs et al., 2011)	Education and problem solving self-management training for a maximum of 9 sessions, aimed at improving HbA1c and reducing cardiovascular risk factors.	Session use data (*Dose Delivered*), audiotaped sessions (*Fidelity*, scoring method unspecified), structured questionnaire (*Participant Experience*).	None reported.
Keogh et al, 2011, Ireland (Keogh et al., 2007)	MI for 3 sessions, aimed at improving HbA1c, altering illness perceptions and improving psychological wellbeing.	Session data (*Dose Delivered*), quantitative and qualitative analysis of a sample of audiotapes and interventionist field notes (*Fidelity*).	Open-ended questionnaire, focus group (*Participant Experience*).
Waker 2012, USA (Waker, 2012)	MI for two 60-minute sessions, aimed at improving HbA1c and self-management behaviours.	Session data (*Dose Delivered*), quantitative rating of audiotaped sessions (*Fidelity*),	Structured and open-ended questionnaires (*Participant Experience*).
Blackberry et al, 2013, Australia (Blackberry et al., 2013)	Educational and empowerment based 'telephone coaching' for 15 months, aimed at improving HbA1c.	Session data (*Dose Delivered*)	Focus groups pre-trial exploring health professionals views on self-management (*Formative Evaluation*), sample of sessions recorded and rated qualitatively, research staff field notes (*Dose Received, Fidelity*), interviews and focus groups (*Participant Experience, Provider Experience*).
Gabbay et al, 2013, USA (Gabbay et al., 2013)	MI over a 2-year period, aimed at improving HbA1c.	Session data (*Dose Delivered*), sample of audiotaped sessions rated quantitatively (*Fidelity*).	Focus groups (*Participant Experience*).
Jansink et al, 2013, The Netherlands (Jansink et al., 2013)	Education, lifestyle counselling and MI for 14 months aimed at improving HbA1c, diet and physical activity levels.	Session data (*Dose Delivered)*	Follow up meeting/focus groups (*Patient Experience, Provider Experience*).
Keane et al 2014, Australia ((Goode et al., 2015)	Telephone counselling over 18 months, aimed at increasing physical activity and promoting weight loss and improving HbA1c.	Session use data *(Dose Delivered, Dose Received)*	None reported.

Discussion

Summary of Findings

None of the studies identified for review reported process evaluation data on all 12 components of process evaluation outlined in Chapter 3, and none of the studies reported process evaluation data on *Recruitment, Contamination* or *Adoption*. These components may provide valuable data on mechanisms of impact within an intervention. For example, the study of *Recruitment* may be able to tell researchers how their chosen method of recruitment is or is not reaching the target population they want to study, or if there is a participation bias. An example of this could be a study that recruits participants via the postal service, and which may potentially under-recruit as participants may find letters easier to ignore than a phone call where they are actively engaged with a researcher. The reason that observations about *Recruitment* or *Contamination* were not reported by any study reviewed may be that they are more likely to be reported as study limitations than as a component of process evaluation. No studies reported any assessment of intervention *Adoption*, which may be due to limitations in resources. At present, process evaluation research is under-developed and it is unlikely that researchers are considering putting adoption evaluation strategies in place.

Aside from components on which no data were reported, the most understudied components were *Formative Process Evaluation*, *Dose Received, Provider Experience* and *Barriers and Facilitators*. *Formative Process Evaluation* pre-trial can reveal the acceptability and feasibility of a new intervention to its potential participants and also within its organisational setting. For example, a pilot study using focus groups may reveal the acceptability of an intervention to participants, which may inform design of the main RCT. It may also be crucial for specifying theoretical constructs upon which an intervention is based, which in turn allows researchers to clearly identify which constructs and their components contributed towards outcome. It may be that this is an under represented component of process evaluation due to financial and time constraints as many research teams may not have resources to carry out feasibility studies or other pre-trial research. However, a comprehensive process

evaluation should ideally be implemented at all stages of research design including formative stages, during trial implementation and post-trial. It is noteworthy that in the lifespan of this PhD, the NIHR has updated its requirements for funding of RCTs, requiring formative evaluation of pilot studies before funding will be granted (NIHR, 2017).

Provider experience may also be crucial in determining 'how and why' an intervention did or did not work. Many studies explored participants' experience of taking part in their study but did not extend this to providers. Again, this may be due to lack of resources. Providers may also be more difficult to engage, and may be keen to claim back time having already committed valuable resources to the study. They are also smaller in number than participants and represent a smaller potential sample, resulting in a study being under powered if many decline to participate.

Studying *Barriers and Facilitators* to protocol implementation can also reveal important processes that may be crucial for informing the design of future interventions. In some cases it may be that barriers and facilitators were explored as part of *Participant Experience*, but these data were not reported, particularly if the process evaluation was not published separately from the main RCT.

Dose Delivered was always studied as a result of its being a requirement of the CONSORT checklist for the reporting of RCTs. The next most studied components were *Dose Received*, *Fidelity* and *Participant Experience*. Potential reasons for this include (i) the concepts of *Dose Delivered* and *Dose Received* are some of the most established components of process evaluation (ii) *Fidelity* is an established and familiar concept within the literature, developed prior to that of process evaluation theory and (iii) *Participant Experience* represents a low resource option for collecting further data, as consent has been obtained and contact pathways between the research team and participant established.

The most commonly used methodology was quantitative session usage data measuring *Dose Delivered*. This was followed by rated audiotapes of intervention sessions, structured questionnaires and open-ended questionnaires. Observational data and interview studies were the least employed methodologies.

What Did the Process Evaluation Data Tell Us?

Over the past 20 years many RCTs have tested the effectiveness of psychological interventions designed to improve outcome in poorly controlled T2D. The majority of RCTs tested group or individually delivered, low intensity interventions based on CBT, MI, or a combination of both. These psychological interventions were commonly delivered by primary care practitioners or other non-specialist healthcare professionals with little or minimal training in intervention techniques.

The literature review shows that the effect sizes of these RCTs are getting smaller and we must find out why. For example, if the design of future interventions continue to incorporate psychological techniques delivered by non-specialists, we need to know which are the best candidates for training, and the best ways to support them. If future research continues to focus on low-intensity psychological techniques, we must reveal their mechanisms of action (e.g. the collaborative relationship between patient and provider), by collecting qualitative process data. Process evaluation can offer possible explanations for diminishing treatment effects and provide researchers with a research strategy going forward.

Strengths and Limitations of This Literature Review

There are a number of strengths to this literature review. This is the first review of process evaluations of psychological interventions designed to improve glycaemic control in T2D. It therefore represents an important step in furthering understanding of the current state of process evaluation research in this field. It is also, to our knowledge, the first literature review of process evaluations of RCTs of psychological interventions designed to improve outcomes in any long-term condition.

The literature review was also conducted using data from two systematic reviews of RCTs of psychological interventions designed to improve outcome in poorly controlled T2D (Ismail et al., 2004). There is no consensus on conducting a process evaluation, and therefore no consensus on how to conduct a literature review in the area. This approach added to the literature in a meaningful way, rather than starting

afresh. A further benefit of adopting this approach is that the literature was narrowed to a field more relevant to this thesis, exploring process evaluations of studies relevant to the T2D epidemic. The inclusion criteria for the review were generous, including studies that specified they had conducted a process evaluation, and also those which did not. This approach was chosen with the aim of identifying all attempts at process evaluation, despite terminological variation. It was then possible to synthesise studies without being limited by wide variation in terminology and frameworks, which in turn enabled more meaningful comparisons between studies. Establishing an a priori framework allowed for structured discussion proceeding from theoretical deduction rather than simple observation.

However, there are a number of important weaknesses. The review could not include process evaluations of RCTs of interventions conducted in different contexts, e.g. in community settings. The findings may therefore not be generalisable to other types of intervention in different long-term conditions. Much process evaluation work has taken place within the health education context, which this review does not include. It is possible therefore, that developments within the process evaluation field may have been missed due to the exclusion of this category. This work was conducted to inform the wider findings of the D6 Study, and therefore focused on psychological interventions in T2D in order to make parsimonious use of limited resources. The scoping study described in Chapter 3 demonstrated that process evaluation studies conducted within the health education context are numerous and may have provided a deeper understanding of the field. However, conducting a literature review of all process evaluations carried out within different settings and populations represents an amount of work far beyond the scope of this thesis and more equivalent to several PhDs.

A systematic review of process evaluations of occupational stress management interventions alone identified 84 studies that met inclusion criteria. The authors identified stress management interventions conducted within health, education and industrial settings, which utilised diverse methods including assertiveness training, structural re-organisation, relaxation and information giving. The framework outlined by Linnan and Steckler was used to identify process evaluation components measured (Linnan, 2002). The authors concluded that the quality of process evaluations between

studies was highly variable and the link between process and outcome evaluation rarely assessed. They also concluded that while the framework of Linnan and Steckler was a 'useful guide' for the conduct of process evaluation, it may be advisable to consider the addition of other components to the framework which are appropriate to the occupational stress management context, such as 'change in intermediate outcomes' (Murta et al., 2007). This suggests that specific adaptations may be necessary for use within specific contexts, underlining the importance of conducting focused research before attempting generalisation to other contexts.

Finally, it is not possible to discriminate with certainty between process evaluations that were not reported, and those that were not conducted at all. Researchers may have conducted evaluations but not published their findings.

Future Research

Future process evaluation research should work towards consensus on components of process evaluation studied and methods used. Process evaluation data should be reported and synthesised with RCT findings. At present there is wide variation in process evaluation frameworks and the field is on the cusp of rapid development.

This represents an exciting challenge for researchers. We must begin employing these methods to uncover reasons for the downward trend in effect sizes of RCTs which are not performing as well as their underpinning theories would predict. Process evaluation can answer questions such as (i) are we using the wrong theory to predict behaviour change? (ii) are the psychological techniques employed being delivered incorrectly, or by the wrong people? (iii) are these psychological techniques being delivered to the wrong patient group? We can begin to offer explanations for results *before* interventions are redesigned or replicated.

Conclusions

This review highlights inconsistency and the limited extent in the elements of process evaluation reported in the literature and methodology used. Historically, researchers

have been unaware of process evaluation and the development of the field has been haphazard, conducted on an individual basis in the absence of formal guidance. Funding bodies did not require researchers to plan for process evaluations and there is no process evaluation education as part of clinical trials training (Council, 2015). Including process evaluation guidance in CONSORT guidelines for example would mean researchers are required to include it in their research design. The aims of process evaluations have therefore been inadequately defined and many studies conducted a minimal process evaluation, adding just one or two other elements to their main RCT design. Among studies which did carry out evaluations, results were rarely fully reported, nor discussed within the context of the main trial findings and it may be that in some cases, data were collected but not reported. In general, limited attention has been applied to linking the aims of an evaluation with informing improved intervention implementation and understanding of outcomes. Methodologically, the field of process evaluation seems to be one where 'anything goes'. There is a lack of consistency and it is very difficult to apply assessments of quality or make meaningful comparisons. There is therefore a clear need for a process evaluations framework which can be followed in a linear manner, in line with the format of the CONSORT checklist for RCTs. Process evaluation aims should be clearly stated and their link with specific outcomes clearly defined. Findings should be discussed in the context of main trial outcomes. The field of process evaluation needs to catch up with the measurement of RCTs in terms of importance and quality of assessment, in order to sit alongside CONSORT. The process evaluation framework proposed and tested in this review shows promising results and offers a credible starting point.

The next chapter outlines the RCT on which the framework was tested.

Chapter 5: The Diabetes 6 Study

Chapter Summary

The previous chapter applied a process evaluation framework to a systematic review of RCTs of psychological interventions to improve glycaemic control in T2D, described and summarised the components of process evaluation studied and the methods used.

This chapter presents the protocol of D6 and its ITT findings. D6 is a cluster RCT comparing the effectiveness of a nurse led psychological intervention designed to improve glycaemic control in people with T2D. The methods and findings of process evaluations 1 and 2, which assess the components of *Dose Delivered* and *Dose Received* are also presented.

Background and Clinical Problem

Suboptimal glycaemic control in T2D remains a major health problem despite the implementation of intensive medical regimens following landmark research such as the UK Prospective Diabetes Study (UKPDS) (King et al., 1999). The UKPDS was a randomised, prospective, multi-centre trial of glucose lowering agents. It convincingly found that the rate of progression of complications of T2D, previously regarded as unavoidable, could be reduced by improvements in glycaemic control and/or BP (UK Prospective Diabetes Study Group, 1998). Intensive insulin therapy in patients with T2D was associated with reduced risk of micro-vascular and macro-vascular complications, and these results were shown to persist at 10-year follow up (Holman, Paul, Bethel, Matthews, & Neil, 2008). Optimum glycaemic levels remain difficult to achieve in the T2D population, despite this landmark study and those similar. For example, an RCT of a stepwise intensive behavioural treatment versus standard treatment of risk factors with microalbuminuria, designed to slow the initiation and progression of microvascular complications in microalbuminuric patients with T2D, found significantly lower rates of progression to nephropathy, progression of

retinopathy and progression of autonomic neuropathy than those in the usual care group (Gæde, Vedel, Parving, & Pedersen, 1999) (Wallace & Matthews, 2000).

This spurred the development of educational programs to support self-management. DESMOND (Diabetes Education and Self Management for Ongoing and Diagnosed), a diabetes education and self-management course considered a cornerstone of T2D management, was interpreted as effective in improving knowledge about T2D and improving quality of life. However the UK National Diabetes Audit suggested that prevalence of uptake of structured education programs for newly diagnosed T2D vary between 0 and 48% (HSCIC, 2012). Reasons for this vary and include psychological barriers such as shame and stigma of diabetes (Winkley et al., 2016), provider barriers with primary care professionals not referring and organisational barriers such as frequency, location and marketing of the educational programs.

Other initiatives include the QOF for diabetes, introduced in primary care (Calvert et al., 2009), where significant responsibility for the care of patients with T2D now falls (Kane, 2001). However, the system has failed to benefit T2D patients with persistent sub-optimal control (Calvert et al., 2009). QOF aimed to improve quality of care via a system of financial reward for general practice surgeries for delivering a minimum number of care processes such as recording of HbA1c, BP and changes in patient health status. Indicators for diabetes constituted the largest of any clinical area, yet a follow up study found that the QOF approach had failed to capture patients with suboptimal control in its assessment (Calvert et al., 2009).

The reasons for persistent sub-optimal control despite these major adaptations to national guidelines are multifactorial, and psychological barriers such as depression and diabetes-specific worries related to managing the multiple self-care tasks required of patients represent a major part of the problem. Rates of depression are increased two-fold in diabetes compared to the general population and it is associated with reduced self-management (Ciechanowski et al., 2000a; Egede & Zheng, 2003), poorer glycaemic control (Lustman et al., 2000) and a 2-5 fold increase in mortality (Katon et al., 2005) (Ismail, Winkley, Daniel, Chalder, & Edmonds, 2006). Diabetes specific psychological worries include difficulties in accepting and adjusting to the diabetes diagnosis including shame, self blame, guilt; worries and fears about potential

diabetes complications, fear of self-testing and injecting, fear of hypoglycaemia and fear of insulin therapy, concerns about body image and weight gain and disordered eating (Peyrot et al., 2005a).

Role of Psychological Treatments in Management of Type 2 Diabetes

Based on the observation that there is a high prevalence of psychological problems in T2D and that these are likely to be associated with reduced self management, there is face validity that psychological treatments may be an important adjunct in contributing towards improved glycaemic control in a population where pharmacological interventions alone may be effective but not as efficacious (UK Prospective Diabetes Study Group, 1998). Patients are required to perform a variety of self-care behaviours in order to achieve optimum glycaemic control, including dietary modification, exercise, self-monitoring of blood glucose, foot care, and adherence to medication. Psychological therapies can help by establishing a rapport between patient and therapist in which they are able to work collaboratively to identify, challenge and modify health beliefs and barriers to these self-care tasks (Nicholson et al., 2009).

Psychological treatments used commonly in medical settings in the UK include MI and CBT. MI is a brief (usually 1 to 4 sessions) counselling style designed to enhance motivation to change problematic health behaviors by exploring and resolving ambivalence about change (Rollnick & Miller, 1995). CBT is a longer therapy (usually a minimum of 6 to 12 sessions) that aims to enable the patient to identify, challenge and substitute unhelpful cognitions and behaviors with more constructive ones (Beck, 1963; Lang, 1970). It is a method of eliciting thoughts via Socratic dialogue, which encourages the patient to identify their own problematic thoughts through questioning enquiry. This uncovers the possibility of alternative thoughts, which can be assimilated into a strategy for behavioural change (Beck, 2011). Examples of Socratic questions include, ‘what have you found has worked for you before? Was there ever a time when you were having more success with this?’

Could Health Professionals Deliver Psychological Care in Diabetes?

Experts in both diabetes and psychological techniques are rare and costly (Roberts, 2007), and their expertise is best reserved for a small but highly complex group of multi-morbid patients (Katon et al., 2005; Trude & Stoddard, 2003). However, there are large sub-groups of people with T2D, mostly in primary care, who struggle to achieve optimal glycaemic control despite intensive medical therapies. It may be that health care professionals who deliver usual diabetes care could use specific psychological techniques to manage less severe but more common barriers to self-care (Alam et al., 2009). If practice nurses can be trained to competently deliver integrated psychological and diabetes care, this would represent a potentially cost effective opportunity to expand their existing role as providers of diabetes counselling, while simultaneously reducing the level of burden on psychological services and on patients (Nicholson et al., 2009). The use of MI and CBT skills is associated with clinically and statistically significant improvements in glycaemic control in hospital patients with T1D (Ismail et al., 2008a), but there is little evidence that these techniques can also be delivered to T2D patients by primary care healthcare professionals such as general practice nurses.

One systematic review found no difference in the reduction in HbA1c in those interventions delivered by 'generalists' (pooled mean reduction 0.51% (95% CI: -0.50 to 0.04: 9 RCTs with a sample size of n=832) compared to psychotherapists (0.57% (-0.36; 95% CI: -0.61 to 0.12: 9 RCTs with a sample size of n=561) (Alam et al., 2009). It was concluded that training generalist clinicians in psychological therapies could represent a viable pathway to improved outcome in subgroups of T2D patients with sub optimal glycaemic control.

There is evidence in substance misuse settings that integrating CBT and Motivational Enhancement Therapy (MET) may increase its efficacy (Haddock et al., 2003; Miller & Rollnick, 2002; Parsons, Rosof, Punzalan, & Maria, 2005). MET is closely related to MI in that whereas MI was originally developed as 1 session MET has a few more sessions, typically 4. During the lifetime of this thesis, the term MET is barely used and subsumed into the MI label. In a multi-centre, three arm parallel RCT, when these 2 therapies were combined, it was found that this combination was associated with an HbA1c reduction of just

less than 0.5% compared to usual diabetes care in people with poorly controlled T1D but MET on its own was not (Ismail et al., 2008a). This method of integrating MI and CBT as an intervention to improve glycaemic control was yet to be tested in T2D.

Main Hypothesis

Diabetes care delivered by practice nurses trained in a set of 6 psychological skills based on MI and CBT, is more effective than usual diabetes care delivered by practice nurses in improving glycaemic control in people with T2D and persistent suboptimal glycaemic control over 18 months.

Secondary Hypotheses

(i) Diabetes care delivered by practice nurses trained in psychological skills is more effective than usual diabetes care in reducing cardiovascular risk factors (body mass index, lipids, BP)
(ii) Practice nurses trained in psychological skills are more effective in improving a) depression and b) diabetes related psychological wellbeing than practice nurses who do not receive the training
(iii) Diabetes care delivered by practice nurses trained in psychological skills is more cost-effective than usual care in improving diabetes control
(iv) The number of D6 intervention sessions attended is associated with sustained improvements in diabetes control.

Design and Setting

A definitive 2 parallel arm cluster RCT. Cluster randomisation was employed to avoid contamination between experimental conditions. Clusters were moderate to large GP practices (defined as having ≥ 6000 patients registered), set within the Lambeth, Southwark, Lewisham, Wandsworth and Bexley Primary Care Trusts (PCT) (now referred to as Clinical Commissioning Groups). Surgeries with list sizes < 6,000 patients were invited to combine

into one cluster in order to meet the requirements for sample size. This represented a population of 1.43 million patients who were invited to take part if they attended a practice with a practice nurse providing diabetes care. A 2-phase approach to cluster recruitment was adopted in order to address slow recruitment as a result of organisational challenges faced due to the imminent implementation of the Health and Social Care Act 2012. This Act involved significant reorganisation of NHS structures relating to management, funding, accountability and regulations (The National Archives, 2012).

Study Population and Study Criteria

The target population was people with T2D and persistent sub-optimal glycaemic control, despite primary care team delivery of NICE guidelines adapted for local settings. The diagnosis of T2D by primary care physicians in South London was based on WHO clinical criteria. It was anticipated that 5000 registered patients would have an HbA1c >7.4% of whom ~ 2500 would have persistent HbA1c ≥9.0% based on data from QOF (Gulliford, Naithani, & Morgan, 2007). Index of Multiple Deprivation rank score was used to assess relative deprivation of GP surgery locations (Department for Communities and Local Government, 2015).

Inclusion Criteria

(i) Adults aged between 18-79 years
(ii) Duration of diabetes for ≥ 2 years since diagnosis
(iii) Persistent suboptimal glycaemic control defined as HbA1c ≥ 64 mmol/mol% (equivalent to 8%) on two occasions, once in the past 18 months and HbA1c at time of recruitment. Original inclusion criteria required one HBA1c result but this was amended via research ethics committee to better capture a persistently poorly controlled population. It had been previously lowered from 69.5mmol/mol% (equivalent to 8.5%) to 64 mol/mol (equivalent to 8%), in order to boost recruitment.

Exclusion Criteria

(i) Severe mental disorders, defined as schizophrenia; manic depression; depressive psychosis; active suicidal ideation; learning disability; dementia; alcohol and substance dependence; severe personality disorders; terminal illnesses and severe end stage diabetes complications
(ii) Morbid obesity with a BMI >50kg/m2 (as this group of patients typically have concurrent serious medical problems)
(iii) Housebound, or dependent on a formal carer (patients were required to attend the surgery for regular face to face appointments)
(iv) No phone or Internet access (these methods were options for the delivery of part of the intervention)
(v) Patients who were unable to speak conversational English (as D6 is a talking therapy)
(vi) Patients undergoing psychotherapy at the time of recruitment
(vii) Patients with Patient Health Questionnaire-9 (PHQ-9) scores >20 were reviewed by the research psychiatrist or their GP to assess if s/he should be excluded in case they had psychotic depression or were actively suicidal.

Recruitment

Eligible GP practices were invited to participate by the PCT diabetes champion, clinical leads, general practice managers, the primary care research network (PCRN) and the research team (not including the PhD candidate). GP practices were offered financial compensation for their participation (£10,000 per practice). If more than 1 nurse provided diabetes care at a participating practice, the lead GP selected the most appropriate nurse to participate in D6. Phase 1 recruitment of practices took place from 1st June 2010 – 30th September 2010. Phase 2 recruitment of practices took place from 1st October 2010 – 29th April 2011. Participant recruitment took place from 1st September 2010 – 29th July 2011 for Phase 1 and 1st March 2011 – 31st October 2011 for Phase 2. The practices' electronic diabetes registers were screened for all current cases of diabetes and a list of all those potentially eligible was generated. The lead GP (for diabetes) sent letters to potentially eligible patients describing

the study and inviting participation. Interested patients were invited to meet a D6 researcher, usually at the patient's own practice, to complete baseline clinical data collection and study questionnaires. At that visit, they were asked to undertake an additional fasting blood test. The researcher also accessed each participant's medical notes to confirm patient histories with regard to medical history and therapies.

Each baseline data collection visit took approximately 60 minutes. If the researcher did not take a fasting blood sample at this initial visit, an extra attendance at the practice or other local phlebotomy service was required.

Randomisation and Allocation Concealment

Randomisation of the GP surgeries (unit of cluster) was conducted by an independent clinical trials unit using a random number generator to assign equal numbers of surgeries to each arm at each of the two waves. Allocation concealment was conducted by holding the randomisation list by an independent manager in a password-locked computer. Randomisation of clusters was intended to take place after all patients had been recruited but in this pragmatic trial this was leading to unacceptable delays in the training of nurses and some patients were recruited after randomisation of the general practices but this information was not given to the researcher or the patient until all baseline data were collected. Baseline data were collected before randomisation and research workers were blind to allocation for the outcome assessment. Participants were not blind as the intervention was a talking therapy.

Research Team

The core research team comprised Professor Stephanie Amiel (Chief Investigator); Professor Khalida Ismail (Co-Investigator); Dr Kirsty Winkley (NIHR Post-Doctoral Fellow); Dr Nicole DeZoyza (Clinical Psychologist); Dr Daniel Stahl (Trial Statistician); Dr Anita Patel (Health Economist); Chris Turner (Research Assistant and Trial Manager); Helen Graves (Research Assistant and PhD student) and Sarah Mann (Research Assistant).

Professors Amiel and Ismail were responsible for the design and overall conduct of the trial; Dr Winkley was responsible for the setting up and overall management of the trial; Dr Stahl was the trial statistician, responsible for statistical analysis; Dr Patel was responsible for the health economic assessment; Chris Turner was responsible for data collection and day to day trial management; Sarah Mann and Helen Graves were responsible for recruitment of patients, data collection, management of D6 nurses and trial administration.

Baseline Measures

The following measures were taken at baseline:

Socio-demographic: Age; gender; self-report ethnicity; partnership status; number of children; employment status and occupation and educational attainment data were obtained from the patient by the D6 research assistant.

Biological: A fasting blood sample was used to measure HbA1c; lipid profile; full blood count; thyroid function and fasting plasma glucose. Incidence of hypoglycaemia for the last year and history of cardiovascular disease were taken by history from the patient and checked against their GP practice medical records. Date of diagnosis and HbA1c results from the last year were also obtained from records. Albumin:creatinine ratio to examine nephropathy was measured in a random urine sample; retinopathy was assessed from the most recent fundal photograph from the community based eye complication screening services; neuropathy was measured using 10g monofilament, and vibration perception testing using a biosthesiometer was assessed by the D6 research assistant, as were BP and BMI.

Psychological: Depression was measured using the PHQ-9, a self-report 9-item depression screening questionnaire (Kroenke, Spitzer, & Williams, 2001); the Self Care Inventory-Revised version was used to assess adherence to diabetes related self-care activities (Weinger, Butler, Welch, & La Greca, 2005); the Diabetes Distress Scale was used to assess severity of diabetes related thoughts and stressors (Polonsky et al., 2005); the Diabetes Fear of injecting and Self Testing Questionnaire was used to measure fears around blood glucose testing and administering insulin (Mollema, Snoek, Pouwer, Heine, & van der Ploeg, 2000);

The Barriers to Insulin Treatment Questionnaire was used to assess concerns regarding insulin use (Petrak et al., 2007); Dysfunctional Attitude Scale to assess depressogenic cognitions (Weissman & Beck, 1978); Brief Illness Perception Questionnaire to measure health beliefs (Petrie & Weinman, 1997); Current Cognitive Status was assessed using the Wechsler Test of Adult Reading (Wechsler, 2001), the Telephone Interview for Cognitive Status [TICS-M] (Brandt, Spencer, & Folstein, 1988), the Trail Making Test (Reitan, 1992), the Rey Auditory Verbal Learning Test (Schmidt, 1996) and the Verbal Fluency Test.

Economic: Quality of Life was measured using the Short Form 12 Health Status Questionnaire to measure quality of life (Ware Jr, Kosinski, & Keller, 1996) and other economic evaluation data using the Client Service Receipt Inventory (CSRI) for a retrospective period of 6 months (Chisholm et al., 2000).

Description of Intervention

Group 1: Usual Care Attention Control

As there is marked variation in usual care for people with sub optimal T2D control, practice nurses delivered usual care as recommended by NICE and adapted for the local population (NIHR, 2002). To control for attention effects, practice nurses in both usual care attention control and intervention groups were required to see patients for the same number of appointments at the same frequency. Patients were therefore invited to attend 6 x 30 minute face to face sessions followed by a further 6 face to face sessions in a format agreed with the patient (phone, email, or face to face).

Group 2: Usual Care Plus D6

Usual care based on NICE guidelines continued as described above. In addition, the D6 intervention was designed to address psychological problems that may have been contributing to sustained suboptimal glycaemic control.

The D6 intervention took place over 6 face-to-face sessions and a further 6 sessions in a format agreed with the patient. Each session was up to 30 minutes and delivered at the following frequency: Sessions 1-6 (fortnightly), Sessions 7-10 (monthly) and Sessions 11-12 (two monthly). The focus of the intervention was on increasing the patient's motivation to improve their diabetes control in the first instance. The nurse and patient then worked collaboratively to address key self-care behaviours such as medication adherence, self-testing, physical activity and dietary changes.

A summary of skills used in the D6 intervention is presented in Table 5.1.

Training of D6 Nurses

Training in D6 skills was provided by an experienced clinical psychologist in the form of interactive training workshops and regular supervision. Interactive training workshops were conducted over 12 x 3 hourly sessions and the nurses provided with the D6 handbook for ongoing reference (see Appendix IV). Nurses were trained in 6 D6 skills, including active listening, managing resistance, directing change, supporting self-efficacy, addressing health beliefs and shaping behaviours. These are summarised in Table 5.1. The overall aim was to enhance patients' motivation to improve their diabetes control by collaboratively addressing key self care behaviours such as adherence to medication, blood sugar monitoring, dietary changes and physical activity levels. Training emphasised that the overall 'spirit' of MI and attitude of the clinician was more important than focusing on the specific skills. Nurses were required to practice D6 skills by integrating them into consultations with their existing diabetes caseload. Nurses attended monthly supervision with the trial clinical psychologist either in person at group sessions provided at King's College Hospital or over the telephone if they were unable to attend. As a last resort, email support was provided on an individual basis. Nurses were required to record all D6 consultations on a digital recorder provided by the research team (used to assess fidelity, described in Chapter 6) and to provide a sample recording for monthly supervision, which was reviewed by the clinical psychologist.

Table 5.1: Summary of Skills Taught in D6 Intervention (The D6 Training Manual provided in Appendix V)	
Skill	**Content**
Active Listening	In active listening, the patient is seen as the 'expert' and the clinician resists the reflex to tell them what is best. The clinician demonstrates interest and empathy, which form the building blocks of therapeutic rapport. Active listening forms the cornerstone of motivational interviewing. Active listening includes the use of open questions, affirmations, reflections and summaries, as well as elements of non-verbal communication. Open questions allow the patient to provide more information rather than a simple 'yes or no' response, enabling the clinician to learn more about their motivation to change and shifting the balance of power towards the patient. Affirmations are statements made by the clinician that demonstrate support. These may include statements that show support for the patient's behaviour, show support for positive attributes e.g. aptitude for multitasking or validate their efforts in managing their condition. Reflections show the patient that the clinician has listened and understood what they have said. A simple reflection includes a basic acknowledgement of what the patient has said, while a complex reflection adds something more. This may involve strategic use of a statement to emphasise ambivalence, roll with resistance or elicit change talk. Summaries are reflective statements allow the clinician to pause, summarise and reflect on a consultation. Often, a summary can provide an opportunity to redirect the consultation.
Rolling with Resistance	How to side step resistance and maximise collaboration with the patient. Resistance is a normal part of the change process and occurs when the patient and clinician are at different stages of change. Skills used to assess readiness to change and move patients forward in a collaborative way are therefore important. Techniques involved in managing resistance include dealing with barriers to active resistance, dealing with avoidance (passive resistance) and dealing with highly emotive situations.

	Techniques include: (i) Selective Attention to focus on the 'green shoots', which arise from a mixture of positive and negative statements from the patient. The clinician focuses on the most positive 'green shoot' statement and redirects attention towards it. (ii) Positive Reframing may be used to reframe the patient's negative statement, providing a more optimistic view. (iii) Overshooting Reflections involves inflating the patient's statement to create an opportunity for positive change talk. (iv) Asking a 'Typical Day' question can prompt patients with little to say to reflect on their usual activities, providing non-threatening subject matter. (v) Asking a 'Values Question' may be useful for patients in the precontemplation stage of change. Talking about other areas of life can provide a useful starting point for a conversation that examines how the patient's day to day life impacts their diabetes control. (vi) Normalising involves communicating to the patient that their difficulties in managing their condition are normal, which gives them permission to communicate their struggles. (vii) Providing a Simple Reflection may be helpful in diffusing an emotive situation. (viii) Taking a One Down Position can provide relief in a hostile situation. The clinician acknowledges shared responsibility for a challenge faced by the patient, enabling them to redirect the consultation.
Directing Change	This introduces a range of techniques to bring about 'change talk' in the patient including decisional balances, eliciting patient values, developing discrepancy between goals and current behaviours, and adapting the consultation to match the stage of change of the patient. DARN Questions are used to direct change by encouraging patients to express their own reasons for change. DARN is an acronym for Desire ('wants, wishes, likes'); Ability ('can, could, able'); Reason (stating a specific reason for change); and Need ('need to, must have, important'). Questions are designed to elicit DARN statements (and therefore change talk) from patients.

	Amplifying Change Talk. When change talk happened it should be acknowledged and amplified. The 'green shoots' should be encouraged to grow. Providing affirmations, encouraging elaboration and selective attention techniques may be used. CAT Questions are used once a patient is ready to act, are designed to move the patient closer to activation and address potential barriers. Cat is an acronym for Commitment ('will, intend, going to'); Activation ('ready, willing to'); and Taking steps ('reporting recent action towards change').
Supporting Self Efficacy	This includes ways to elicit solutions or coping strategies from the patient rather than the clinician. It considers how to provide clinical information in a way that doesn't undermine patient autonomy. Techniques for supporting self-efficacy include Affirmations and Solution Focused Questions. A clinician makes an affirmation when they highlight a behaviour the patient has successfully performed and explicitly acknowledge the link between their actions and any positive consequences. Solution Focused Questions involve eliciting change talk through the use of CAT questions and other questions designed to enable patients to draw on their own resources.
Addressing Health Beliefs	Includes techniques to elicit unhelpful health beliefs, which might be standing in the way of behaviour change and provides nurses with tools e.g. visual aids to address common misperceptions in diabetes and skills to monitor a patient's understanding. Identifying underlying health beliefs is the first step and may present challenges when the patient themselves is not aware of their beliefs or they may be unwilling to share them. This underlines the importance of building rapport between patient and clinician (e.g. Active Listening). Techniques used to elicit health beliefs may be 'upward arrow' or downward arrow'. Upward arrow questions involve asking the patient why x behaviour is *beneficial* to them with the aim of identifying a gap in knowledge. Downward arrow questions involve asking the patient why x behaviour is *detrimental* to them with the aim of finding out what the patient is misunderstanding or distorting. Once an understanding of health beliefs has been gained the clinician may begin forming new ones (cognitive restructuring). This may include working with unhelpful thinking style including catastrophising, personalising, providing 'all or nothing' responses, discounting the positive, over generalising and subjective reasoning.

Shaping Behaviours	This includes techniques to help patients who are ready to change e.g. problem solving, goal setting, core anxiety management and supporting behaviour change by setting realistic goals, encouraging experimentation and managing setbacks. Goal setting involves breaking down a large task into smaller, non-threatening steps. Goals must be SMART: Specific, Meaningful, Attainable, Rewarding and Time based. In order to support the patient the clinician may play devil's advocate. This enables the discussion of potential setbacks and solutions. Anxiety management may take the form of controlled breathing exercises, progressive muscle relaxation and distraction techniques. Positive reinforcement may be used to provide rewards for positive behaviour change. Problem solving techniques may include brainstorming, assessment of pros and cons, and experimentation.

Adherence to The Protocol

Deviations from the intended 6 face-to-face treatment sessions and additional 6 sessions represent the dose of the D6 intervention delivered to patients. The minimum intended dose of the intervention to satisfy adherence by the patient was 1 session, and this was considered the minimal effective dose of the intervention, in line with MI interventions in diabetes and primary care populations (Heinrich, Candel, Schaper, & de Vries, 2010) (VanBuskirk & Wetherell, 2014). As variation in the timing of visits was anticipated, the visit window was defined as the number of sessions completed with the 12-month period. For example, if the patient was seen 3 times only within 12 months, they were not offered further sessions. The time interval between each session was recorded. Intervention dose delivered will be reported as numbers (% of intervention group) of patients attending each session.

Adherence to the D6 intervention was measured using the Motivational Interviewing Treatment Integrity Scale (MITI) (Moyers, Martin, Manuel, & Ernst, 2007) and the Behaviour Change Counselling Index (BECCI) (Lane, 2002). Adherence to the protocol by practice nurses was assessed by review of audiotaped intervention sessions. Both measures and their data are described in detail in Chapter 6.

To be MI adherent nurses were required to score >90% on the 'Beginning Proficiency subscale and >3 on the Empathy subscale of the MITI. These subscales were chosen because MI Adherence and Empathy have been shown to be predictive of treatment success (Apodaca & Longabaugh, 2009; Moyers & Miller, 2013). Nurse competency is described in detail in Chapter 6.

Loss to Follow Up and Other Missing Data

When a patient wished to withdraw from the trial, consent was sought to retain existing data and to continue to collect data from the patient's routine care. If appropriate data on T2D control could be collected within an appropriate time frame, they were included. Main analyses used follow-up data at 15 and 18 months post-randomisation, with a 3-month

window either side. For the analyses data taken at 15 months ± 1.5 months was used for the 15 months follow-up measurement and ± 1.5 months as follow-up measurements for 18 months. If several measurements for 18 months existed the one closest to 18 months was chosen.

Statistical Analysis

The trial statistician conducted the D6 data analysis. Data were analysed using STATA 9. The sample characteristics were described. Twenty-nine participants with HbA1c <64 mmol/mol (equivalent to 8%) contrary to the study criteria were included and this represented a protocol violation. We performed a sensitivity analysis by including a binary covariate of this protocol violation (yes/no) in the model. ANCOVA was used to estimate differences between MI and the usual care attention control group in HbA1c level at 18 months using baseline HbA1c and other possible confounding variables as covariates. Subsidiary outcomes (such as lipids and weight) were analysed in the same way. Treatment effects on secondary outcomes at 18 months (fasting triglycerides, BP, BMI, quality of life, Client Service Receipt Inventory and Depressive symptoms) and longitudinal effects of HbA1c levels of the invention groups over the time course of the study were assessed in a similar way, using generalisations of the linear mixed model to allow for non-normal distributed data where necessary.

Power Calculation

A 10·9 mmol/mol difference in HbA1c in D6 compared to standard care was the minimal clinically acceptable reduction at 18 months taking into account: (a) baseline HbA1c and (b) that standard care may produce a 2·2 mmol/mol (equivalent to 0·2%) reduction in HbA1c for the placebo effect of participating in a RCT (actual difference between groups 8·8 mmol/mol (equivalent to 0·8%), equivalent to a moderate effect size of d=0·55). Assuming 20% dropout, we needed 360 patients at 80% power at two-sided alpha-level of 5%. Therefore 20

practices with 18 patients per arm required. We took account of clustering by practice. Assuming two practices per arm dropped out, we needed 24 practices with a total patient size of 24 x18=432 patients. The required sample size adjusted for a clustering intra-correlation coefficient (ICC) effect of 0·05 was 81x1·7=138 patients per arm (inflation factor 1·7).

We recruited 334 patients of which 231 had at least one follow-up in 24 clusters. The average cluster size was therefore 10 patients per cluster, smaller than our assumed size of 15 patients per cluster with a post-hoc power of 77% (STATA 13 *clsampsi* function) at two-sided alpha-level of 5% (Batistatou, Roberts, & Roberts, 2014).

Process Evaluation

The ideal process evaluation would study all 12 process evaluation components as outlined in Chapter 3. A full process evaluation was planned, however due to limited time and resources the following 8 components were studied. The reasons for this are discussed further in Chapter 9.

Recruitment: recruitment strategies were consistently reassessed and amended for the duration of the RCT recruitment period.

Dose Delivered: assessed via records of attendance at D6 sessions.

Dose Received: assessed via records of attendance at D6 sessions. Multilevel modelling was used to determine the developmental trajectories of HbA1c across the 18 months to determine the association between number of sessions and other potential covariates and rate of change of HbA1c.

Fidelity: assessed via a sample of audiotaped D6 intervention sessions and independently rated using the MITI and BECCI. Full methods and results are reported in Chapter 6.

Contamination: Assessed using audiotaped D6 intervention sessions and everyday contact

with D6 nurses. Research Assistants were required to provide support to nurses participating in the study, regularly meeting to address problems they were experiencing in adhering to D6 protocol.

Provider Experience: assessed via semi-structured interviews with nurses who took part in D6. Full methods and results are reported in Chapter 7.

Participant Experience: assessed via semi-structured interviews with participants in D6. Full methods and results are reported in Chapter 8.

Barriers and Facilitators: assessed via semi-structured interview of participants and nurses who took part in D6. Full methods and results are reported in Chapters 7 and 8.

The components of *Formative and Theoretical Evaluation; Formative Acceptability and Social Validity; Context* and *Adoption* were not formally studied part of this thesis but are discussed in Chapter 9.

Results of The D6 Study

Figure 5.1 shows the recruitment and randomisation timeline of D6. Of 116 GP practices invited, 26 agreed to participate. Two practices dropped out prior to randomisation, which took place on 29th October 2010 and Phase 2 on 27th May 2011. One D6 practice dropped out after randomisation, before the nurse received the training, and before all patients were recruited (those who consented remained in the ITT analysis). Twenty-four GP practice clusters were randomised, with three clusters formed by combining two practices.

Across all clusters, there were n=995 potentially eligible participants identified from the diabetes registers. Of the n=451 who consented for eligibility and participation, n=334 were recruited. Twelve practice clusters were randomly assigned to standard care (n=164 patients) and 12 to standard care plus D6 (n=170). One D6 practice dropped out after randomisation, before the nurse received the training, and before all patients were recruited (those who

consented remained in the ITT analysis). Invited practices that participated (n=24) compared to those that did not (n=89) had higher mean patient list sizes (12180 (SD 5099) vs. 10091 (SD 3894), p=0·03) but no difference in Index of Multiple Deprivation rank score (10049 (SD 6910) versus 12441 (SD 7785), p=0·17).

Protocol Violation

A protocol violation at the beginning of recruitment meant that 29 patients were recruited into the study with a baseline HbA1c <64 mmol/mol (equivalent to 8%).

Figure 5.1: Recruitment and Randomisation Timeline of D6

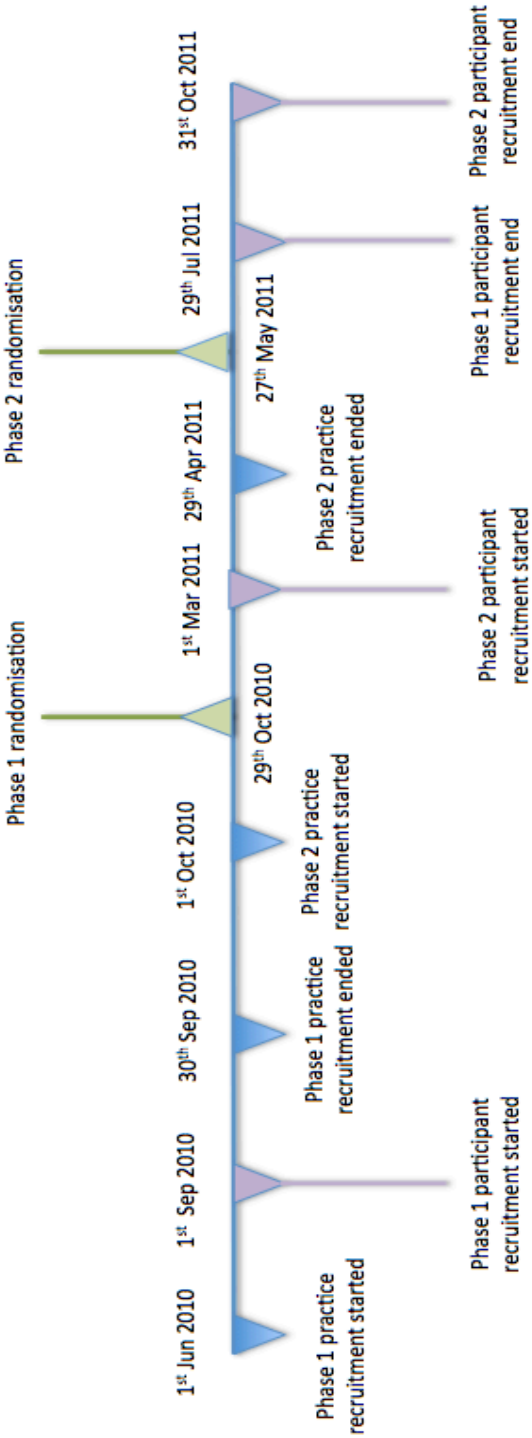
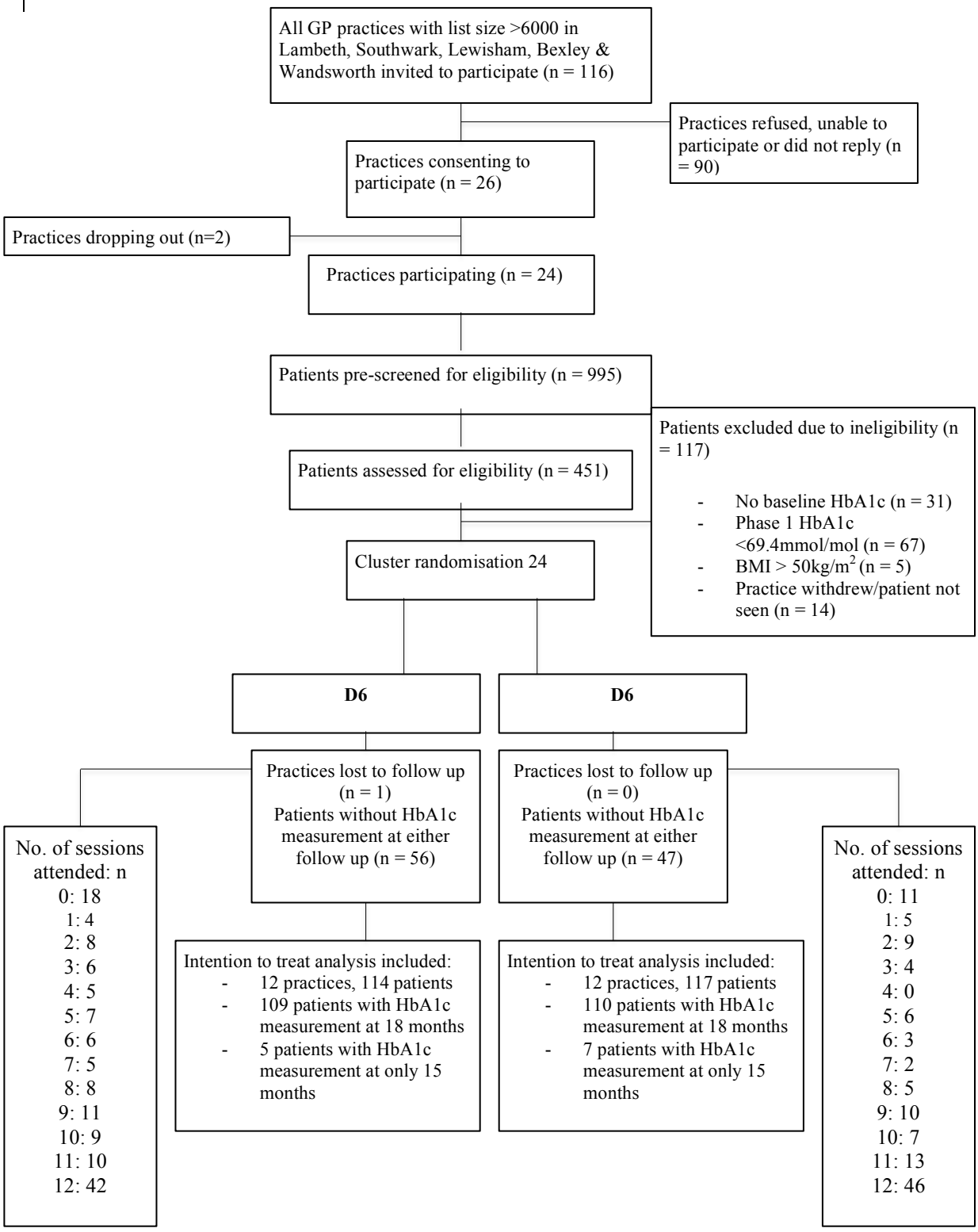


Figure 5.2: CONSORT Flow Diagram for The D6 Study



Sample Characteristics

The mean age of participants was 58·9 years (SD 11·2), 51·2% were female, and the proportion who were White, African/Caribbean or Asian/Other was 40·4%, 43·1% and 16·6%, respectively. The median duration of diabetes was 9 years (interquartile range 5–12 years) and 43·0% of patients were taking insulin at baseline. The mean HbA1c was 80·5 mmol/mol (SD 18·1) (Table 5.2).

Table 5.2: Baseline Characteristics of Participants Randomly Assigned to Receive D6 or Standard Care

Variable*	D6 (n=164)	Standard Care (n=170)	Total
Age (years)	59·0 (11·1)	58·9 (11·4)	58·9 (11·2)
Gender			
Male	82 (50·0%)	81 (47·7%)	163 (48·8%)
Female	82 (50·0%)	89 (52·4%)	171 (51·2%)
Ethnicity			
White	60 (36·8%)	74 (43·8%)	134 (40·4%)
African/Caribbean	81 (49·7%)	62 (36·7%)	143 (43·1%)
Asian/Other	22 (13·5%)	33 (19·5%)	55 (16·6%)
Relationship status			
Married or Cohabiting	82 (50·3%)	89 (52·7%)	171 (51·5%)
Separated/Divorced/Widowed	52 (31·9%)	45 (26·6%)	97 (29·2%)
Single	29 (17·8%)	35 (20·7%)	64 (19·3%)
Education level			
A levels or higher	47 (29·2%)	43 (25·8%)	90 (27·4%)
O level or GCSE equivalent	68 (42·2%)	48 (28·7%)	116 (35·4%)
No formal qualifications	46 (28·6%)	76 (45·5%)	122 (37·2%)
Employment			
Yes[1]	69 (42·1%)	70 (41·2%)	139 (41·6%)
No[2]	95 (57·9%)	100 (58·8%)	195 (58·4%)
Borough			
Lambeth	83 (50·6%)	42 (24·7%)	125 (37·4%)
Southwark	25 (15·2%)	40 (23·5%)	65 (19·5%)
Lewisham	19 (11·6%)	52 (30·6%)	71 (21·3%)

Table 5.2 continued			
Wandsworth	37 (22·6%)	24 (14·1%)	61 (18·3%)
Bexley	0 (0·0%)	12 (7·1%)	12 (3·6%)
Diabetes duration (years)	10 (7–13)	9 (5–12)	9 (6–12)
BMI (kg/m^2)	32·0 (5·6)	31·9 (6·6)	31·9 (6·1)
Systolic blood pressure (mm/Hg)	135·2 (16·9)	133·2 (17·3)	134·2 (17·1)
Diastolic blood pressure (mm/Hg)	79·5 (9·8)	79·0 (10·3)	79·2 (10·1)
Total cholesterol (mmol/L)	4·3 (1·1)	4·2 (1·2)	4·2 (1·2)
Fasting triglycerides (mmol/L)	1·7 (1·2)	1·7 (1·3)	1·7 (1·3)
Taking insulin			
Yes	75 (46·3%)	66 (39·8%)	141 (43·0%)
Any retinopathy			
Yes	59 (35·9%)	65 (38·2%)	124 (37·1%)
No	105 (64·0%)	105 (61·8%)	210 (62·9%)
Albumin:Creatinine ratio			
Negative	65 (59·1%)	83 (69·8%)	148 (64·6%)
Positive	45 (40·9%)	36 (30·3%)	81 (35·4%)
Protein:Creatinine ratio			
Negative	33 (76·7%)	17 (77·3%)	50 (76·9%)
Positive	10 (23·3%)	5 (22·7%)	15 (23·1%)
Foot ulcers			
Yes	9 (5·6%)	12 (7·1%)	21 (6·4%)
No	152 (94·4%)	157 (92·9%)	309 (93·6%)
Macrovascular disease			
Yes	61 (37·2%)	55 (32·4%)	116 (34·7%)
No	103 (62·8%)	115 (67·7%)	218 (65·3%)

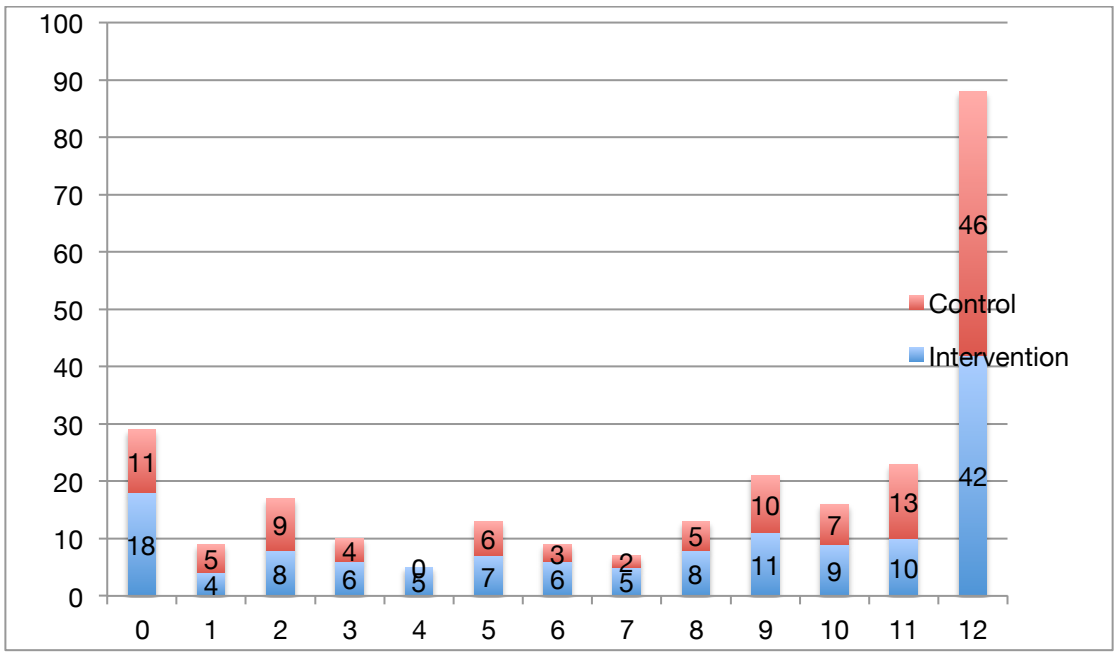
Table 5.2 continued			
Patient Health Questionnaire-9 score			
≥10	31 (20·4%)	35 (22·4%)	66 (21·4%)
<10	121 (79·6%)	121 (77·6%)	242 (78·6%)
Diabetes Distress Scale (mean item score)	2·1 (1·7–2·7)	2·0 (1·6–2·7)	2·1 (1·6–2·7)

Data are n (%), median (IQR), or mean (SD), as appropriate.

[1]Yes = full time, part-time, student or self-employed; [2]No = retired/unemployed/not seeking employment

*Values missing for age (n=1), ethnicity (n=2), relationship status (n=2), education level (n=6), diabetes duration (n=20), body mass index (n=5), systolic blood pressure (n=25), diastolic blood pressure (n=26), HbA1c (n=1), total cholesterol (n=53), fasting triglycerides (n=58), insulin (n=6), albumin:creatinine ratio (n=105), protein:creatinine ratio (n=269), foot ulcers (n=2), Patient Health Questionnaire-9 (n=26), diabetes distress scale (n=27).

Figure 5.3: Number of Sessions Attended by D6 Participants



The mean number of sessions attended was 7·42 (SD 4·4) and 8·20 (SD 4·4) in the D6 and standard care plus attention control groups, based on n=139 and n=121 non-missing observations, respectively.

Primary outcome data at 18-month follow-up were collected for n=219 (65·6%). Twelve participants had missing 18-month HbA1c data but complete 15-month HbA1c data, yielding a total n=231 for the primary outcome analysis. There was a non-significant larger proportion with missing HbA1c in the D6 group compared to standard care (35·9% versus 32·9%, respectively) and were more likely to be African/Caribbean or Asian/Other, with no other differences in baseline characteristics.

In the ITT analysis there was no significant difference in mean HbA1c at follow-up in the D6 group compared to the standard care group (mean difference -0·79 mmol/mol, 95% CI -5·75–4·18) (Table 5.3) The ICC for the clustering effect of nurse was 0·02 (95% CI 0·001–0·37). There was no evidence of an association between the number of D6 sessions attended and HbA1c at 18 months within the D6 group (-0·44 mmol HbA1c per additional session attended, 95% CI -1·28–0·41).

Linear mixed models showed no significant effects of the intervention on the secondary outcomes including BMI, blood pressure, fasting triglyceride or psychological distress (Table 5.3).

Table 5.3: Results from D6 Primary and Secondary Outcome Measures

Outcome at 18 months	Participants with baseline measurements	Participants with measurements at 18 months	Estimated Mean Difference: D6 vs. standard care (95% CI)
Primary			
HbA1c (mol/mmol)*	332	231	-0·79 (-5·75–4·18)
Secondary			
BMI (kg/m^2)*	329	152	-0·08 (-1·12–0·97)
Total cholesterol*	281	140	-0·08 (-0·42–0·27)
Systolic blood pressure (mm/Hg)*	309	198	-1·35 (-6·85–4·14)
Diastolic blood pressure (mm/Hg)*	308	198	1·22 (-1·87–4·32)
Fasting triglycerides**	276	135	0·02 (-0·22–0·26)
Patient Health Questionnaire-9 Score***	308	114	-0·18 (-1·30–0·94)

*Estimates based on linear combination from linear mixed-effects model with fixed effects of time (15 or 18 months), an interaction between time and randomisation group, randomisation phase, borough and baseline values of the outcome, a random effect for GP practice nurse clustering and with unstructured covariance matrix to account for dependency of repeated observations.

**Estimates based on linear combination from linear mixed-effects model with fixed effects of time (15 months or 18 months), an interaction between time and randomisation group, randomisation phase, borough and baseline values of the outcome, a random effect for GP practice nurse clustering and with independent covariance structure due to convergence issues when estimating non-zero covariances.

***Collected at 18 months only. Estimates based on linear combination from linear mixed model with fixed effects of randomisation phase, borough, baseline value and random within-cluster effect of nurse with unstructured covariance matrix to account for dependency of repeated observations.

Results were similar for the sensitivity analysis using practice as the clustering variable in place of nurse as cluster. A sensitivity analysis including a binary covariate for those 29 participants with baseline HbA1c <64 mmol/mol did not show any effect on the primary outcome. Similarly, the sensitivity analysis using multiple imputation to account for missingness in HbA1c showed no evidence of a group difference.

There were 43 serious adverse events reported after 18 months for 38 different participants (n=14 and n=24 in D6 and standard care group respectively). These were coded as cardiovascular (n=11), injury (n=5), cancer (n=4), infection (n=5), diabetes-related (n=3), psychiatric (n=2) and other (n=10). There was no difference in the distribution of serious adverse events between the 2 groups. Two participants died during the trial, secondary to cancer.

Results of Process Evaluation Components Recruitment, Dose Delivered and Dose Received

Recruitment

Due to difficulties recruiting patients from a poorly controlled T2D population, 2 inclusion criteria were amended via research ethics committee.

Original inclusion criteria required one HBA1c result ≥ 64 mmol/mol% (equivalent to 8%) in the past 18 months but this was amended via research ethics committee to 2 HBA1c results ≥ 64 mmol/mol%, once in the past 18 months and once at recruitment, in order to better capture a persistently poorly controlled population.

Due to difficulties in achieving adequate sample size, HbA1c was lowered from 69.5mmol/mol% (equivalent to 8.5%) to 64 mol/mol (equivalent to 8%).

Dose Delivered and Dose Received

Data on *Dose Delivered* were collected as a requirement of CONSORT guidelines for the design and conduct of RCTs. The mean number of sessions attended was 7.42 (SD 4.4) and 8.20 (SD 4.4) in the D6 and standard care plus attention control groups, based on n=139 and n=121 non-missing observations, respectively. *Dose Delivered* and *Dose Received* represent the measurement in a psychological intervention, in contrast to a pharmaceutical intervention for example, when the patient is prescribed a medicine but may not take it.

Discussion

This was a cluster RCT to test the effectiveness of a low intensity psychological intervention to support self-management in people with T2D to improve their glycaemic control and other biomedical outcomes. The main finding was that training nurses in psychological skills drawn from MI and CBT did not result in significant changes in glycaemic control or any secondary outcomes in people with T2D and persistent sub-optimal glycaemic control when compared to usual care with attention control.

Strengths and Limitations

Strengths of this study are that it was a pragmatic design, conducted in a real world, primary care setting in an ethnically diverse area of South London. The sample represented the diversity of the wider T2D population and typical NHS nurses (Gulliford et al., 2007). The D6 intervention was developed in line with the current evidence base, underpinned by theoretical concepts. This intervention was then manualised, and *Fidelity* of implementation was measured (Chapter 6). In addition, a cluster randomised design was employed in order to reduce the risk of contamination between intervention and control group participants e.g. if an intervention nurse were to deliver the intervention to patients in the control group.

Limitations of this study included poor uptake by GP practices invited to participate, at a rate of 20%. Practices were offered backfill payment as an incentive to participate, and to cover the cost of the nurse who would be required to give time to the D6 trial, but many declined despite this. Practices that were privately owned, non-NHS practices did not respond to invitation to participate. A protocol amendment during the course of the study lowered HbA1c inclusion threshold, as recruitment rate of this hard to reach population was slow. BMI was also raised to 50kg/m. Sensitivity analyses showed that these changes did not alter effect size. There was also a protocol violation at the beginning of recruitment which saw n = 29 patients recruited below minimum HbA1c requirements. Sensitivity analysis showed that this did not affect primary outcome.

Can the process evaluation help explain the non-significant findings?

The literature review in the previous chapter found that the majority of RCTs of psychological interventions to improve outcome in T2D were low intensity designs delivered by non-specialists. D6 shared these characteristics. However, where most RCTs have been subjected to minimal process evaluations, 8 of the 12 components of process evaluation outlined in Chapter 3 were applied to D6 (with the remaining 4 components discussed in Chapter 9).

Patient attendance at D6 sessions was problematic, with average 50% attendance rate, meaning they did not receive the full 'dose' of D6 intervention. No dose response relationship was observed. These results may be explained by the fact that D6 focused on reaching a population with established, poorly controlled T2D who were reluctant to engage with healthcare providers. Patients were also difficult to engage at follow up, with many refusing to attend follow up appointments despite repeated invitation and intensive project management by researchers. Patients had average disease duration of 10 years, yet reported low levels of diabetes related distress, suggesting a state of denial. Chapter 8 explores *Patient Perspectives* and *Barriers and Facilitators* to attendance.

The non-significant results may also be partly explained by nurse factors, explored in the *Fidelity* study in Chapter 6, which found that proficiency in most MI and CBT

domains was sub-optimal and similar to the control group. The qualitative study reported in Chapter 7 explores *Provider Experience* and *Barriers and Facilitators* to intervention implementation, and suggests that this group of nurses did not possess inherent baseline characteristics conducive to the acquisition of psychological skills. The fact that nurses did not self-select to participate in D6 adds credibility to this theory.

Conclusion

D6 represented a novel exploration of the benefits of combining MI and CBT with the aim of improving glycaemic control in patients with T2D and persistent sub-optimal glycaemic control. Results were non-significant with the clinical implication that training primary care nurses in psychological skills does not lead to improvements in self-management in patients with T2D. It may be that MI and CBT do not apply to the T2D population, a possibility since these therapies were developed within the addiction and mood disorders context, for use with patients with alcohol and drug addiction (MI) and depression (CBT). In addition, both of these therapies are designed to target single issues, while management of T2D is highly complex, involving multiple physical and psychological challenges. The need for further research into the most effective therapies for T2D patients is clear, and process evaluation may be crucially important in helping to find the right approach.

Chapter 6: Assessing Fidelity and Competencies of Practice Nurses Delivering Motivational Interviewing and Cognitive Behavioural Therapy to Support Self-Management in Type 2 Diabetes.

Chapter Summary

In Chapter 5, the protocol for the single blind cluster RCT comparing the D6 intervention with usual diabetes care was described. The main ITT findings and quantitative components on *Recruitment, Dose Delivered* and *Dose Received* of the process evaluation were reported.

This chapter describes a study that was conducted as part of the process evaluation of D6. The study aimed to assess the *Fidelity* component of process evaluation as outlined in Chapter 3. The different definitions of treatment fidelity and the rationale and importance for measuring fidelity when attempting to understand the mechanisms of action of a psychological intervention are discussed. The chapter then discusses the methodological complexity of measuring fidelity, particularly in the context of MI. The aims, methods and results of the D6 fidelity study are reported, followed by a discussion of whether they inform a better understanding of why the D6 RCT outcome was negative.

Definitions of Fidelity

A working definition of treatment fidelity is that it refers to 'confirmation that the manipulation of the independent variable occurred as planned' (Moncher & Prinz, 1991).

Several different terms have been used to describe intervention fidelity, including 'implementation fidelity' (Breitenstein et al., 2010), 'fidelity of implementation' (Dusenbury et al., 2003; Sánchez et al., 2007), 'fidelity' (Fixsen, Naoom, Blase, & Friedman, 2005), 'treatment fidelity', (Bellg et al., 2004) 'treatment integrity' (Lane, Bocian, MacMillan, & Gresham, 2004), and 'intervention fidelity' (Santacroce,

Maccarelli, & Grey, 2004). All these terms capture the same underlying construct, namely, is the intervention being delivered as intended? Treatment fidelity is the term that will be used in this thesis to refer to the set of methodologies used to monitor and enhance the reliability and validity of a behavioural intervention.

The Rationale for Considering Treatment Fidelity

Assessment of treatment fidelity and quality of implementation assists in interpreting primary outcomes, provides contextual information, and potentially explains why an intervention did or did not work (Oakley et al., 2006). If the treatment has not been implemented according to protocol, what did the interventionists or therapists then deliver, what is the level of fidelity required for the research community to replicate and/or commissioners to translate it, (Cook, Campbell, & Day, 1979; Glasziou et al., 2010). In the absence of an assessment of fidelity we cannot be sure that an effective intervention was as a result of the intervention itself, or another factor(s) related to the study such as the sample selection, or omitted. Conversely, if an intervention did not work, we cannot be sure that non-significant results were due to the failure of the intervention itself or a failure of implementation. For instance, a classic example of implementation failure was reported as part of an RCT designed to help ex-offenders find employment using a combination of job coaching and one on one sessions with ex-offenders trained in readjusting existing offenders to daily life. However, it was reported that only 1 in 20 participants actually received the intervention as per protocol. This was because of several factors that interfered with implementation, namely an observed bias in which the interventionists appeared to focus attention on a subset of participants, high interventionist turnover, and administrative difficulties which led to delays in contacting participants (Dobson & Cook, 1980). The null outcome could therefore not be attributed to the intervention that was described. The authors concluded that they had evaluated a ‘phantom programme’ and speculated that the original protocol, properly implemented, may have had a positive outcome.

This type of implementation failure is also known as a Type III error, which Scanlon et al defined as follows, ‘Statisticians worry about two type of errors... Type I error is rejecting a hypothesis when it should be accepted; Type II error is accepting a

hypothesis when it should be rejected. Researchers commonly make two other types of errors when conducting process evaluations: Type III error is measuring something that does not exist; Type IV error is measuring something that is of no interest to management and policy makers' (Scanlon, Horst, Nay, Schmidt, & Waller, 1977). A Type III error may lead to potentially effective new interventions being prematurely abandoned, or to ineffective interventions being erroneously adopted (Dobson & Cook, 1980).

Defining the Concept of Treatment Fidelity

Historically, the assessment of treatment fidelity has been problematic as there is no consensus on how it should be conducted (Dusenbury et al., 2010). This has led to different interpretations, making selection of appropriate research methods subjective and making the comparison of fidelity between different studies difficult. A review article published in 1991 attempted to synthesise fidelity research drawn from subject areas of clinical psychology, behaviour therapy, psychiatry and marital family therapy (Moncher & Prinz, 1991). The review evaluated 359 'treatment outcome' studies, conducted between 1980-1988, assessing the extent of their assessment of fidelity. The review concluded that, although there had been significant improvements in the assessment of treatment fidelity, the majority of the studies (55%) had omitted to do so. However, the review made an important contribution towards the assessment of the quality of previous fidelity research, by identifying methods used to train those delivering complex interventions; the procedures used to promote fidelity in intervention delivery; aspects of treatment studied; methods used for assessing fidelity and extent of utilisation of treatment fidelity assessment in the interpretation of results.

Some researchers have defined treatment fidelity as an all-encompassing concept, comprising exposure, dose and participant engagement (Dane & Schneider, 1998), while others have suggested that multiple components must be studied separately in order to achieve a comprehensive picture of treatment fidelity. This latter approach is supported by literature reviews of fidelity studies, which have concluded that studies

have included too few components when assessing intervention fidelity (Dane & Schneider, 1998; Dusenbury et al., 2003).

In process evaluation research, fidelity is defined as a distinct concept alongside other process evaluation components. For example, in their framework for process evaluation, Linnan and Steckler defined fidelity as 'the extent to which an intervention was implemented as planned' (Linnan, 2002). They then considered this concept of fidelity as useful in combination with the concepts of 'dose' and 'reach' in creating a picture of overall treatment implementation.

This is theoretically similar to the concept of treatment fidelity later adopted by the MRC in their process evaluation guidance (Moore et al., 2015). They refer to a definition which defines fidelity as a combination of 'content' (similar to Linnan and Steckler's fidelity), frequency and duration of delivery (similar to Linnan and Steckler's dose) and 'coverage' (Linnan and Steckler's reach) (Carroll et al., 2007). In this framework, fidelity is moderated by factors such as intervention complexity, with a more complex intervention considered more difficult to assess for fidelity than a simple one (Carroll et al., 2007; Hasson, 2010).

The most recent guidelines for process evaluation produced by the MRC propose a definition of treatment fidelity but do not provide specific guidelines for the assessment of treatment fidelity of complex psychological interventions, instead giving general descriptions of methodologies, with no recommendations for a gold standard method. This leaves us a better understanding of the construct but no consensus on what should be measured and how (Moore G, 2014).

A concept of fidelity now commonly used in RCTs of psychological interventions is therapist adherence and competence (Boswell et al., 2013; Mars et al., 2013; Martino et al., 2008; Santacroce et al., 2004). The constructs of adherence and competence are separate but related. According to Mars et al (Mars et al., 2013) adherence is defined as 'the extent to which a person delivers the essential content, delivery strategies and theories prescribed by the intervention designers and avoids activities proscribed by them' while competence refers to 'the level of 'skill' demonstrated by those delivering an intervention and may include the ability to respond appropriately to a

wide variety of contextual cues.' Assessing adherence to the planned intervention alone does not give a comprehensive picture of overall fidelity (Dusenbury et al., 2003). Adherence is frequently measured at the programme level of implementation, where it refers to the extent to which implementation of the intervention in the target setting was consistent with that set out in protocol. Competence is less frequently measured and occurs at the individual level (Cross & West, 2011).

Defining Competence

Therapist competence is defined as, 'the extent that a given treatment is conducted in accordance with the instructions or intentions of the respective treatment manual' although historically experts have disagreed on the definition (Kazantzis, 2003). Early definitions focused on therapists' ability to engage the client in a beneficial therapeutic relationship (Cooper, 1975; Strupp, 1986). Definitions were later expanded to include multiple dimensions which argued the importance of basing therapeutic programmes on theoretical approaches (Schaffer, 1983). In recent years, there has been increased interest in competency-based practice in line with increased demands for accountability, leading to a 'competencies based movement' (Kaslow & Keilin, 2006). A multidimensional definition of competence defined by Kaslow includes 'intervention competencies' and specifically the assessment of competencies within RCTs. A review of studies assessing the relationship between therapist competence and therapeutic outcome found small but positive correlations between therapist competence and patient outcome in several limited domains and concluded that larger sample sizes are needed to more accurately capture clinical effect. For example in one trial of CBT versus usual care in reducing recurrent deliberate self harm, a random sample of 49 audiotape CBT sessions delivered by 21 therapists was rated to assess therapist competence. At 6 month follow up there was a small but statistically significant relationship between therapist competence and observer rated depression. There was no association between therapist competence and number of self harm episodes during follow up (Davidson et al., 2004). A small number of studies demonstrated no relationship between therapist competence and therapeutic outcome with the authors speculating that this may be due to the restricted range of competencies among experienced therapists. For example, in a study examining the

influence of therapist adherence and competence in delivering emotion focused therapy on client reprocessing of child abuse memories, no significant effect on symptomatic improvement was observed (Paivio, Holowaty, & Hall, 2004). The reviewers concluded that more studies including a wider range of competencies (e.g. among trainees or non-specialists) is needed (Barber, Sharpless, Klostermann, & McCarthy, 2007).

A further challenge is the assessment of competence over time. A traditional view was that once a therapist achieves competence they retain it for a lengthy period of time e.g. months or years. However, studies have shown great variation in therapists' performance in delivering MI over time (Forsberg, Forsberg, Lindqvist, & Helgason, 2010). A pilot study assessing the effects of a two day MI training workshop for staff working within probation services found that therapists showed an increase in MI skills after training completion, but that these skills were not maintained at 3 month follow up (Miller & Mount, 2001), while another found that behavioural health providers with low baseline skills showed a decrease in newly acquired MI skills at 4 month follow up (Moyers et al., 2008). Interventions that are observed as effective in the original RCT often are less effective when implemented into routine care. One explanation could be that the level of competency and fidelity was higher in the RCT and could not be replicated when translated into clinical practice but because the level of competency was not measured we do not know what skills to teach at what level and what level of supervision is needed for maintenance of these skills (Fixsen et al., 2005). If interventions are to be adopted in practice by different therapists with different levels of expertise, it is essential that researchers understand the level and degree of fidelity and competency required to implement an intervention reliably (Glasgow et al., 2003). It is now argued that even the most experienced therapists require continued competence assessment (Kazantzis, 2003).

Despite widespread use of MI and CBT, many studies do not assess the competence with which they were delivered (Lai, Cahill, Qin, & Tang, 2010; Moyers, Miller, & Hendrickson, 2005b). Therapists vary widely in a number of characteristics, which may affect the delivery of a psychological intervention. These may include: motivation to engage with the practice of MI (nurses may not be interested in adopting an enhanced role); interpersonal skills (e.g. nurses may not have sufficient

capacity to empathise) and previous training (some nurses may have previous experience of psychological skills training) (Moyers et al., 2005b). This potential for variation may be further increased when acquiring and using MI skills falls outside the therapist's usual job remit for example the qualitative study described in Chapter 7 found that GP practice nurses trained in psychological skills aimed at improving self-management in T2D found that nurses lacked confidence to step outside their established role (Graves, Garrett, Amiel, Ismail, & Winkley, 2016).

The Fidelity Versus Adaptation Debate

While it is crucial to assess whether or not an intervention was implemented according to protocol, there is a debate in the literature about the relative merits of adhering strictly to protocol for the study duration, versus allowing room for changes to sampling strategies, timings, localities and other factors (Shen, Yang, Cao, & Warfield, 2008). Some researchers argue that 'true' fidelity to the protocol is necessary, that adaptation is a mistake (Szulanski & Winter, 2002) and that programme modification makes evaluation across different settings challenging (Boruch & Gomez, 1977). Others argue that programmes must be modified to local conditions to 'maximise efficiency as well as local ownership' (Fairweather & Tornatzky, 2013; Shen et al., 2008). Differences in local populations, resources, budgets and organisational factors may all necessitate changes to protocol (Johnsen et al., 1999). Many researchers therefore posit a mixed fidelity-adaption approach, which identifies which programme components require absolute fidelity to the original protocol and which may be adapted. Several approaches have been proposed. Leff and Mulkern (Leff & Mulkern, 2002) and Kelly et al (Kelly, Heckman, Stevenson, & Williams, 2000) posit an empirical approach involving the deconstruction of protocols and individual testing of components across multiple sites. Components determined not critical in determining outcome may then be adapted across different settings, although the method requires significant resources. Others have posited an approach which allow changes to protocol up to the point of 'drastic mutation', or up to the point at which the programme's integrity would be effected by further dilution (Hall cited in (Blakely et al., 1987), although this method is vulnerable to varying interpretations of 'drastic'. A third approach posits that

changes may be made providing they do not contradict underlying programme theory (Price, Friedland, Choi, & Caplan, 1998). This approach allows staff across multiple sites to adapt programmes to local context.

In an intervention such as D6, which required multiple nurses to deliver an intervention across multiple sites, some adaptation to local circumstances is expected. The potential effects of these adaptations are covered in the discussion section of this chapter.

Measuring Treatment Fidelity

Methods used in the assessment of treatment fidelity of complex interventions include interventionist/clinician self-report; participant self-report; ethnographic data and rating of audiotaped intervention sessions (Mowbray, Holter, Teague, & Bybee, 2003).

Self-Reported Treatment Fidelity

Self-reported treatment fidelity is the most subjective method of assessing treatment fidelity and therefore the most likely to be biased (Carroll et al., 2002). For example, in a secondary analysis of an RCT examining the effects of 2 different supervision conditions on the development of MI skills, therapists reported their use of a variety of MI adherent techniques, but independent observers found a much more limited use of these techniques (Wain et al., 2015). Supervision conditions included tele-conferencing supervision of 5 x weekly counselling sessions including simulated interactions with actors posing as patients. Each session was monitored by a supervisor and who provided real time feedback and written follow up feedback. The second supervision condition was tape-based, for participants who completed 5 x weekly audio taped simulated interactions with actors playing patients. The audiotape was sent to the supervisor who provided written feedback in addition to verbal feedback via telephone. Participants in a 'workshop only' training condition received no feedback. Participants' self-reported ability increased with supervision but self-report was not an indicator of objectively measured increased skill. Similarly, another

RCT found low concordance between therapist self-reports of psychotherapeutic strategies used with children with disruptive behaviour and observer ratings (Hurlburt, Garland, Nguyen, & Brookman-Frazee, 2010). Sixty three videotaped therapy sessions delivered to 18 children and their caregivers in community outpatient clinics by 11 therapists were assessed. Analyses focused on frequency, type and intensity of goals and strategies pursued in therapy sessions. Therapists reported an average of 2.5 more goals and strategies per session than those identified by observational coders. Self-report strategies are therefore too limited by their potential social desirability effects and variation in rater competencies to be valid fidelity assessment tools.

Ethnographic Data

Other methods of obtaining fidelity data include observational data collected by a trained observer (Resnicow et al., 1998), although this method is rarely employed since it is very resource intensive, and has the potential to produce reactions from the therapist and/or patient under observation which may affect any treatment effect and which may not sufficiently reflect real world practice (Sheridan, Swanger-Gagné, Welch, Kwon, & Garbacz, 2009). The observer is likely to be a senior expert of the intervention and will have a vested interest in over estimating fidelity.

Rating of Audiotaped Intervention Sessions

A well recognised standard method for assessment of treatment fidelity is the recording and coding of intervention sessions using audiotape and checklist rating methods (Bellg et al., 2004). Audiotape recordings minimise bias in that they remove potential for subjective reporting of the contents of an intervention session. Reliable and valid checklists can then be used in order to assess (i) dose of the intervention delivered as planned, (ii) dose of the intervention that was delivered to the control group and (iii) to what extent the competence of therapists was maintained during the study. However this too is vulnerable to errors unless carefully monitored: the therapists can 'lose' the equipment or locate it out of recording range; patients and therapists may not give consent; the rater may introduce his/her own biases in rating fidelity by accents, gender.

Assessing Fidelity of the D6 Intervention

Aims

The main aim of this chapter is to assess whether D6 nurses adhered to the manual and whether they had achieved competency in the MI and CBT skills to support self-management in patients with poorly controlled T2D compared to an attention control condition.

Specifically the aim of the treatment fidelity is to examine:
i) Whether D6 nurses achieved competencies in the D6 skills at the start of delivering therapy
ii) To compare these skills with those of nurses in an attention control group.

Methods

Design

All nurses who participated in the D6 RCT were required by protocol to digitally record their appointments with patients. A representative sample of the tapes from both trial arms was selected to assess fidelity and competency. Nurses were randomly allocated to receive training in D6 or to attention control.

The Training Program in D6

The psychological skills training program for nurses in the intervention arm of the RCT was developed and delivered by an experienced clinical psychologist Band 8a. The initial interactive training workshops were conducted over 12 x 3-hourly sessions based on a manual that the nurses could use for self directed learning, revision, reference and clinical aid. The focus of the intervention was on increasing patients' motivation to improve their diabetes control and then collaboratively addressing key self-care behaviours such as medication adherence, blood glucose testing, physical activity and dietary changes.

Techniques Taught in Motivational Interviewing and Cognitive Behavioural Therapy

These psychological interventions are both evidence-based approaches aimed at producing behavioural change in a range of settings, and there is evidence that integrating MI and CBT may be beneficial (Arkowitz, 2004).

MI is a collaborative, person-centred approach to working with people in order to elicit and strengthen their motivation and commitment to change (Miller & Rollnick, 2002). It was originally developed for use in the substance abuse context, when counsellors, particularly those working with alcohol abuse, noted a large amount of conflict within patients, particularly poor motivation, denial and resistance. These qualities were considered ingrained within the clients themselves, until Miller developed the hypothesis that the style in which clients were spoken to may have the potential to either enhance or decrease their level of motivation to change (Miller, 2000).

MI was then developed as a specific counselling style, which provided counsellors with skills to explore the client's uncertainty about change and reduce resistance. A central guiding tenet of the approach is that the motivation to change should come from within the client, and not be imposed upon them by the counsellor. There are three main concepts, which are central to the motivational interviewing approach, as follows:

(i) Readiness: This concept is borrowed from the Stages of Change Model of Health Behaviour (Prochaska et al., 1985), which emerged in parallel with the field of MI and is based on the principle that people have different needs to be addressed, depending on their stage of readiness to change. It provided useful inspiration for the concept of readiness underpinning MI, which states that moving too far ahead of the patient's stage of readiness to change will result in their resistance. Furthermore, readiness underpins two tenets of MI, which are importance and confidence. Importance refers to the individual's evaluation of the importance of making personal

changes, while confidence refers to the person's willingness and confidence in their ability to change.

(ii) Ambivalence: Ambivalence about change refers to the way that a patient may simultaneously feel the desire to change but also the desire to resist it. The job of the therapist is to harness the innate motivation within the client by encouraging them to recognise problems, to express desire to change their behaviour, and to feel that they have the ability to do so. This enable the client to hear themselves expressing the desire for change, rather than simply being told they must do it.

(iii) Sustain Talk: Sustain talk is related to the concept of denial and refers to the reluctance on the part of the client to make any progress. When it becomes clear that the counsellor's views are not congruent with those of the client, resistance occurs.

In addition, there are principles underpinning the practice of MI. These are: 'expressing empathy'; 'rolling with resistance'; 'supporting self-efficacy' and developing discrepancy'.

(i) Expressing empathy: The counsellor makes simple empathic statements and more complex statements designed to highlight aspects of the client's problem that might encourage the resolution of ambivalence.

(ii) Rolling with resistance: This is concerned with the maintenance of harmony throughout the session and it concerns the need to avoid confronting the client directly.

(iii) Supporting self-efficacy: Self-efficacy can predict successful behaviour change (Maddux, 2016). Emphasis is placed on eliciting innate self-efficacy, rather than attempting to impose it directly onto the patient.

(iv) Developing discrepancy: The discrepancy between the client's personal values and desires for the future and the self-destructive nature of their behaviour is not viewed as a problem, but as a potential catalyst for change.

The skills used in motivational interviewing are ‘empathic listening skills’, ‘eliciting self-motivating statements’ (change talk), and ‘responding to resistance’, as follows:

(i) Empathic listening skills: these comprise open questions, affirmation, summarising and reflective listening.

(ii) Eliciting self-motivating statements (change talk): the counsellor elicits arguments for the case to change from the client, rather than imposing them upon the client.

(iii) Responding to resistance: the counsellor should respond constructively to resistance, which can be viewed as damaged rapport between the client and counsellor. The counsellor should acknowledge the patients’ difficulty by focus on the positive.

Techniques Taught in Cognitive Behavioural Therapy

CBT attempts to modify behaviours by altering thoughts, interpretations and assumptions. Negative patterns of thought about the self and about the world are challenged with the aim of changing undesirable patterns of behaviour (Beck, 2011). The approach focuses on difficulties in the present, and relies on an alliance and shared view of the problem between the client and the therapist.

Problems are identified and understood in terms of the relationship between thoughts, feelings and behaviours. This then leads to the development of personal goals and strategies. There are a number of key elements to CBT, which together combine to bring about change; these are as follows:

(i) The therapeutic alliance: a trusting, safe relationship between client and therapist is essential to bring about change (although not sufficient on its own).

(ii) Collaboration: the relationship between client and therapist is viewed as collaborative, with each bringing their own potentially useful resources to the table.

(iii) Formulation: A map or hypothesis of problems is formulated, within the context of an evidence-based, CBT framework.

(iv) Socratic dialogue: A method of communicating which focuses on guided discovery. The client should be gently guided towards the realisation that there are alternative ways of thinking.

(v) Goal setting: Goals are set in between sessions; these goals often include behavioural experiments designed to challenge unhelpful thoughts and assumptions.

Combining Motivational Interviewing and Cognitive Behavioural Therapy

There is evidence in substance misuse settings that integrating CBT and MET may increase their efficacy (Haddock et al., 2003; Parsons et al., 2005). In a three arm parallel RCT, when these two therapies were combined (which meant more sessions), treatment was associated with an HbA1c reduction of 0.5% compared to usual diabetes care in people with poorly controlled type 1 diabetes but MET on its own was not (Ismail et al., 2008a). The combination of MI and CBT as a treatment to improve poor glycaemic control in T2D has not yet been tested and that was the aim of D6.

Clinical Supervision

Nurses attended monthly supervision with the trial clinical psychologist either in person at monthly group sessions or over the telephone if they were not able to attend. E-mail support was also offered for individual cases.

Assessment of Fidelity to Motivational Interviewing

MI is a brief (usually 1-4 sessions) counselling method for enhancing motivation to change problematic health behaviors by exploring and resolving ambivalence about change (Miller & Rollnick, 2002). In order to make meaningful assessments of

treatment fidelity, reliable and valid assessment tools are needed to rate audiotaped intervention sessions. Typical rating scales include (i) the Yale Adherence and Competence Scale (YACS) which includes 3 subscales measuring 'general' aspects of drug abuse treatment (assessment, general support, goals of treatment) (Corvino et al., 2000). Validation of the YACS using data from an RCT indicated that the scales have excellent reliability, factor structure, concurrent and discriminant validity (Carroll et al., 2000) (ii) the Motivational Interviewing Skill Code (MISC) yields global scores on qualitative dimensions of theoretical importance to MI followed by quantitative behaviour counts, and has acceptable psychometric properties (Miller, 2000) (iii) the Motivational Interviewing Process Code (MIPC) comprises 25 items split into two subscales assessing functional and dysfunctional skills, both rated on a 5-point Likert scale however its utility as a measure is questionable as it is not satisfactorily validated (Wallace & Turner, 2009) (Barsky & Coleman, 2001) (iv) the Motivational Interviewing Supervision and Training Scale (MISTS), which comprises behaviour counts and global ratings of aspects of MI, although would benefit from further statistical analysis to assess validity such as factor analysis (Madson, Campbell, Barrett, Brondino, & Melchert, 2005) (Wallace & Turner, 2009) and (v) the Motivational Interviewing Treatment Integrity Scale (MITI) (Moyers et al., 2005a).

The most widely used rating scale of fidelity to MI is the MITI, which has a number of advantages. Its reduced length and complexity compared to the measure which preceded it, the MISC, means that it is useful in training, supervision, and research settings (Madson et al., 2005). It has also been found to have adequate reliability and validity (Moyers, Martin, Catley, Harris, & Ahluwalia, 2003) with an inter-correlation coefficient of .51 to estimate interrater reliability of global ratings for empathy/understanding and .58 for spirit of MI. The ICCs for the behavioural counts ranged from .57 to .96 (Moyers, Martin, Manuel, Hendrickson, & Miller) and these coefficients have been considered adequate according to the classification of clinical significance (Cicchetti, 1994).

The MITI, version 3.0 was used to measure competence and skills used in both groups of nurses (Moyers et al., 2007). The MITI was designed to assess how well or how poorly a therapist is delivering MI. It was designed as both a measure of

treatment fidelity for RCTs with an MI component and as a tool to provide feedback for therapists outside of a research environment.

The MITI comprises two components: Behaviour Counts and Global Scores. Behaviour counts are simple counts of the occurrence of therapist behaviours throughout the interview. In this instance the coder is not required to make any interpretation of quality. Global scores require the coder to select a single number from a 5-point scale to characterise the interaction. Global scores therefore represent a 'global judgement.' The 5 global dimensions rated are Evocation, Collaboration, Autonomy/Support, Direction, and Empathy. Both Behaviour Counts and Global Scores are rated during a single review of a 20-minute segment of a recording. Five summary scores are produced including Global Spirit Rating; Percent Complex Reflections; Percent Open Questions; Reflection-to-Question Ratio and Percent MI Adherent.

The Global Spirit score and Empathy scores were selected as the most relevant measures for assessing fidelity in D6 as they are intended to capture the overall competence of the therapist in using MI, and the extent to which the therapist understands, or attempts to understand the patient's perspective. Since they are comprised of the Evocation, Collaboration, Autonomy/Support scores, these measures were considered superfluous in this instance. Further measures of interventionist behaviours included the use of simple reflections, complex reflections, open questions and closed-ended questions. Scores are also calculated for MI adherent and non-adherent counselling behaviours.

Tools for Measuring Fidelity to Cognitive Behavioural Therapy

CBT is also a brief but longer therapy (usually a minimum of 6-12 sessions) that aims to enable the patient to identify, challenge and substitute unhelpful cognitions and behaviours with more constructive ones (Beck, 2011). Rating scales used to measure therapist treatment fidelity to CBT include the Cognitive Therapy Rating Scale (CTRS), comprising 13 items measured on a 6-point Likert scale with high internal consistency and adequate average inter-rater reliability (Young & Beck, 1980)

(Blackburn et al., 2001). An alternative is the Collaborative Study Psychotherapy Rating Scale (CSRPS) (Hollon et al., 1988) which is composed of 96 items rated on a 7-point Likert scale.

A more general tool used to assess fidelity to behaviour change counseling methods such as MI and CBT is the Behaviour Change Counselling Index (BECCI) (Lane et al., 2005). It is designed to measure fidelity to methods of behaviour change counselling in which the client is encouraged to make their own decisions about positive change. It has therefore been used to measure fidelity to a range of behaviour change techniques (Beck et al., 2015; Spanou et al., 2010) more applicable to CBT (Britton et al., 2015; Olsen, Smith, Oei, & Douglas, 2012).

The BECCI consists of an 11-item checklist across 4 domains, which include Agenda Setting and Permission Seeking; The Why and How of Change in Behaviour; The Whole Consultation and Talk about Targets. The rater scores the degree to which the therapist has performed each item on the checklist on a 5-point Likert scale. Scores on individual items are therefore produced alongside a global score in the form of the BECCI Practitioner Score, produced by calculating the mean of all individual items.

It is a brief, easy to use measure more applicable to D6, where the aim was not to train practice nurses to the level of CBT therapists but to enable them to acquire basic skills in behaviour change techniques. It was included here in order to assess nurses' competence in eliciting patients' thoughts and cognitions, therefore addressing the CBT element of the intervention.

Sampling Procedure

All nurses were required by protocol to digitally record their D6 treatment consultations. Nurses completed training over 3 months. It comprised 3 hours per week, interactive classroom activities, a training caseload (average 3-5 non-study patients), and weekly supervision of audiotaped sessions.

During training, nurses were required to submit the following recorded consultations:

Weeks 2-8: 1 x 10 minute consultation per week, rating themselves via coding form.
Weeks 9-10: 1 x 10 minutes consultation per week with feedback provided from trainer.
Week 11: 1 x 10min consultation submitted for a competency assessment, rated by an independent rater using MITI and BECCI.

However, there were a number of issues with obtaining recordings. Nurses were provided with digital, battery operated devices in order to record their consultations but problems did arise, for example batteries running out, nurses misplacing recorders, nurses forgetting to use recorders, and nurses not realising that the recorder was switched off.

The total number of recordings was 353 recordings from 154 participants (31 participants with one recording; 47 with two; and 76 with three) with 266 of them usable. The sample of recordings from tapes used to assess fidelity was n=69.

Tapes were selected using random sampling stratified by participant. Either 1 or 2 tapes from session numbers 1, 3, and 4 were selected for each participant who had at least 1 recording. The tapes could be of any length with the treatment centre identifiable. Three recordings were under 20 minutes in length, in which case the rater selected the next longest recording for that nurse until a 20-minute segment was reached. In 2 cases recordings were unusable as nurses did not identify themselves and therefore could not be assigned to a surgery.

Two clinical psychologists rated a sample of 20-minute windows of 69 tapes using the MITI, and a third psychologist rated the same sample of tapes using the BECCI. The MITI requires formal training, which the two clinical psychologists had previously undertaken. The BECCI manual requires raters to complete a list of required reading and watch a training video before beginning rating. All raters were blind to treatment allocation.

Data Analysis

Statistical analyses were conducted using SPSS Version 23. To assess inter-rater reliability for the MITI global scores and BECCI practitioner scores, intra-class correlation coefficients were estimated using a two-way mixed model. The model had a fixed effect for rater and a random effect for recording in order to account for clustering and it assessed consistency between individual ratings. As the data were not normally distributed, Wilcoxon-Mann-Whitney tests were used in addition to t tests to compare the nurses' fidelity of delivery of the intervention in comparison to the control nurses.

Results

Sample Characteristics

Twenty-three nurses participated in D6; 11 were randomised to the intervention and 12 to the control group. The mean age of nurses was 48 years (SD 8.47), all were female and the proportion who were White, Black and Asian/Other was 61% (n=14), 26% (n=6) and 13% (n=3) respectively. Nurses worked in GP practices in 5 South London boroughs. Prior training/experience in delivering psychological techniques is presented in Table 6.1. Data were not obtained for 6 nurses as data on previous training were collected after the D6 intervention had finished and these nurses were non-contactable.

Table 6.1: Level of Nurse Training in Psychological Techniques		
	Intervention (n)	Control (n)
Some experience as part of nursing qualification	1	0
MI training as part of Co-Creating Health Program (Foundation)	1	0
1 day or less of MI training	1	1
MI training as part of smoking cessation course	1	1
Module as part of degree course	1	1
No previous training	4	5
No data obtained (non-contactable)	2	4

Inter-rater Reliability

Estimates of intra-class correlation coefficients for the global MITI scores and BECCI practitioner score are reported in Table 6.2. Inter-rater reliability was greater for MITI, where all ratings were for the 20-minute section in the middle of each tape, compared to BECCI, where one coder rated 20-minute windows (due to time constraints) and another rated the full duration of tapes.

Table 6.2: Intraclass Correlation Coefficients for MITI* Global Scores and BECCI Practitioner Score**		
Domain	ICC	95% confidence interval
MITI global spirit	0.87	0.77-0.93
MITI global empathy	0.91	0.86-0.94
BECCI practitioner score	0.71	0.49-0.85
*MITI: Motivational Interviewing Treatment Integrity Scale (Moyers et al., 2007); **BECCI: Behaviour Change Counselling Index (Lane, 2002)		

Nurse Adherence

The mean number of sessions attended was 7.42 (SD 4.4) and 8.20 (SD 4.4) in the D6 and standard care plus attention control groups, based on n=139 and n=121 non-missing observations, respectively. Nurses therefore completed just over half of the 12 sessions per patient specified in the protocol.

Nurse Competency

The trial manager, who was MITI trained, assessed post-training adherence and competency of all nurses in the intervention group using the MITI and BECCI rating scales. One tape was submitted by each nurse at the end of training and rated on each of the 2 scales. Thresholds provided by the MITI manual were considered too high for the context of this study, where consultations included clinical communications that would not be part of a standard MI consultation but part of the role of the practice nurse (for example, a physical examination, prescribing, and giving medical advice when requested or deemed clinically necessary). Instead, nurses were rated as non-adherent if they advised, confronted, or directed the patient. Any such nurses were given extra training then reassessed. It was assumed that nurses who were being adherent to the manual but who did not meet minimum MITI competency levels were expected to continue to improve with extra supervision.

Assessment of competency after training in the intervention group ranged from 56 - 100% with mean average 86% competency. This is lower than the percentage MI-adherent threshold for 'beginning competency' score of 90% stated in the MITI training manual. One nurse did not reach minimal competency post-training. She was therefore given extra training by the clinical psychologist and upon reassessment was found to be competent to deliver the therapy. Fidelity data measured during the intervention were missing for 5 nurses, primarily because of faults with the tape recordings. Mean MITI and BECCI competency scores post-training are presented in Table 6.3.

	Table 6.3: Nurse Competence Scores Post-Training (mean; SD)
Global Spirit	3.42 (0.67)
Global Empathy	4.09 (1.04)
% MI Adherence	0.86 (0.16)
BECCI	2.78 (0.50)

Fidelity Analysis

Mann-Whitney U tests revealed a significant difference in the MITI scores of nurses in the intervention and control arms of the RCT on the % Open Questions scale (U = 350, z = -2.79, p = 0.005), with nurses in the intervention group asking significantly more open questions than those in the control group. A significant difference between the two groups was also observed on the Reflection/Question Ratio scale (U = 750, z = 2.12, p = 0.03), with nurses in the control group having a higher ratio of reflections to questions. No significant differences were found between the 2 groups on Global Spirit (U = 454, z = -1.51, p = 0.13), Global Empathy (U = 456, z = -1.54, p = 0.12), % Complex Reflections (U = 646, z = 0.84, p = 0.40), or % MI Adherent (U = 508, z = -0.85, p = 0.40).

A t-test showed a significant difference in the BECCI practitioner scores of nurses between the treatment arms, with a higher score in the intervention group ($t(262)=5.75$, $p<0.001$, 95% CI 0.23-0.47).

Mean scores for MITI and BECCI summary scales by treatment group are presented in Table 6.4.

Table 6.4: Mean Scores for MITI and BECCI Summary Scales by Treatment Group

MITI Domain	Control Group Mean (SD)	Intervention Group Mean (SD)	MITI Minimum Mean Competency (proficiency benchmark)
Global Spirit	2.87 (0.90)	3.23 (1.12)	4 (3.5)
Global Empathy	2.49 (0.98)	2.91 (1.26)	4 (3.5)
% Complex Reflections	0.40 (0.17)	0.35 (0.20)	50 (40)
% Open Questions	0.25 (0.14)	0.36 (0.17)	70 (50)
Reflection/Question Ratio	1.0 (0.83)	0.65 (0.42)	2 (1)
% MI Adherent	0.54 (0.28)	0.58 (0.32)	100 (90)
BECCI practitioner score	1.07 (0.48)	1.42 (0.51)	

Discussion

This chapter describes the fidelity assessment of D6, a nurse-led psychological intervention in the context of a cluster RCT aimed at improving persistent sub-optimal glycaemic control in people with T2D. Nurses who received D6 training asked more open questions and fewer reflections in relation to questions during D6 consultations than control group nurses. They also had higher BECCI practitioner

scores. However, no significant differences in competency levels were found between the 2 groups on the majority of MITI summary domains.

A strength of this study is that quantitative methods were employed to measure fidelity, with experienced MI practitioners using standardised rating scales. Conducting quantitative fidelity analysis is rare. Keogh et al conducted an RCT to test the efficacy of a family-based MI intervention designed to improve outcome in patients with T2D versus usual care. They observed significantly reduced HbA1c in the intervention group versus control at 6 month follow up and significant improvements in beliefs about diabetes, psychological well-being, diet, exercise, and family support. Fidelity was assessed via a sample of audiotaped intervention sessions, rated qualitatively and quantitatively using (unspecified) MI and illness perceptions checklists. Results are not reported, although the authors state that 'the intervention was delivered per protocol' (Keogh et al., 2011). By contrast, Gabbay et al conducted a 2-year pragmatic RCT to examine the effect of MI delivered by Nurse Case Managers (NCMs) compared to usual care control in improving outcome in patients with T2D. Significant improvements in HbA1c were observed within groups but did not differ between groups at the end of the study. Fidelity was measured monthly by MI experts using the BECCI and NCMs were given on-going feedback based on this evaluation. It is reasonable to conclude therefore that significant improvements in HbA1c were due to the intervention. The effect did not persist over time, however, and there was substantial loss of active engagement with the nurse (32%) during the follow up period (follow up HbA1c values were obtained from clinical records). This may account for the lack of significant reduction in HbA1c observed at 2-year follow up (Gabbay et al., 2013).

The sample size could be considered a further limitation of this study, although the 69 tapes rated represent almost a third of the potential sample. Issues with quality and length of recordings plus time and budget constraints made increasing sample size impossible. It is possible that some consultations of interest were missed due to issues with recordings.

It is also possible that the quantitative assessment scales did not fully capture treatment fidelity in this sample of non-specialists. The MITI has been criticised for

its lack of sensitivity in capturing overall clinician competence. Although it is able to capture MI relevant attributes such as empathy and use of micro skills, it may not provide adequate assessment of principles such as eliciting change talk, a complex MI skill which is important when attempting to capture overall therapist competence and fidelity (Madson & Campbell, 2006) (Wallace & Turner, 2009). This may mean that the measure fails to make an accurate overall assessment, particularly during training. However, it has also been suggested that the MITI may be best suited for measuring entry level competence or foundational level skills in MI, which have been shown to account for 70% of client engagement during an MI session (Moyers et al., 2005a).

There are a number of possible reasons why D6 nurses did not deliver the intervention with high fidelity. This includes the possibility that training was not sufficient; nurse factors such as difficulty learning MI skills; pressure to participate in D6; performance anxiety and contamination; patient factors such as difficulties in accessing a hard to reach population and the lack of a D6 pilot study.

Fidelity is comprised of adherence + competence (Boswell et al., 2013; Mars et al., 2013; Martino et al., 2008; Santacroce et al., 2004). As nurses delivered, on average, only 1 more than half the intervention sessions required by the D6 protocol they could not be considered adherent. In terms of competence, analysis of a random sample of sessions showed that proficiency in most MI and CBT domains was below beginner proficiency level and similar to standard care, suggesting that these real-world practice nurses could not be trained in basic psychological skills using the protocol in this study. Nurses particularly struggled to deliver complex reflections and may have benefited from further training in this skill. It may be that the nurses, relatively lacking in MI skills compared to specialised psychologists, were dependent on manualised MI instructions. Manual guided MI has been found in meta-analysis to adversely affect levels of patient-centredness (Hettema et al., 2005).

The aim of this study was to assess nurses' competency post-training as part of the fidelity analysis of D6, therefore competency over time was not measured. However, assessment of competency over time may have shown whether nurses increased or decreased in competency, or stayed the same for the duration of the study, providing

important process evaluation data and having implications for the training of non-specialists in psychological skills.

Despite starting at a reasonably equal level of clinical experience as nurses, it may be that some would have benefited from extra training or supervision. Although the group format of supervision sessions allowed for peer learning, perhaps some nurses needed additional intensive individual training and supervision but neither the nurse nor clinical psychologist had the resources for this.

There may not have been enough time in the session to integrate diabetes care with delivery of psychological techniques, and the task of delivering diabetes nursing care simultaneously with psychological therapy was too complex in practice. This is a skill that may require advanced training perhaps suited to nurse practitioners with pre-existing psychotherapist skills. This possible reduction in the potency of 'pure' MI may also have contributed to lower fidelity ratings, as there was not sufficient time in each session to deliver MI.

Nurses did not self-select to participate in D6. The recruitment of GP practices for cluster randomisation was made via the practice manager, senior GP or diabetes GP lead in the first instance. They were then responsible for identifying and allocating a diabetes nurse from their practice to take part in the study. Some nurses were more enthusiastic about their participation than others, and the results of a separate qualitative nurse study, reported in Chapter 7, support this theory. Nurses were resistant to recruitment into the study and difficult to retain. It is possible that we ignored warning signs that nurses were under pressure in an effort to maintain study momentum.

Nurses were aware that they were being audiotaped and may have felt pressure to use skills effectively, a situation that has the potential for negative effects on performance in addition to social desirability effects. Additionally, although D6 appointments were longer than standard clinical appointments, nurses were required to submit a ten-minute segment for assessment, and it may be that not all skills rated as part of the fidelity assessment were present during this segment.

Other factors that may have influenced nurses' ability to deliver the intervention to protocol include patient barriers, for example some patients were highly resistant and may have presented a challenge to experienced psychologists. This is a difficult to engage, high-risk clinical group with a duration of T2D averaging 10 years, plus persistent hyperglycaemia yet low levels of diabetes distress, suggesting a state of denial. This is explored further in the qualitative study described in Chapter 8.

Findings are further complicated by evidence of contamination in the control group in one instance, where a nurse who was disappointed not to be randomised to the intervention group made extra effort to research D6 skills and deliver them to patients. In fact, the control group may have been counter-productive. The 2 groups differed significantly on reflection/question ratio, although this difference was not in the expected direction. Nurses in the control group used significantly more reflective statements in relation to questions than nurses in the intervention group. It is possible that control group nurses spent more time talking in an effort to fill the extra appointment time, due to the attention control design of the trial. Nurses were required to spend extra time with patients, but did not receive any direction on how use this time, except to provide care as usual.

Multiple adaptations to local circumstances were made which raises questions within the context of the fidelity versus adaptation debate (Shen et al., 2008). Local changes implemented across study sites included variation in the time of day that D6 researchers were able to see D6 patients in their respective surgeries due to restrictions on space and opening hours. In addition, some patients were required to make an extra visit to a local phlebotomy service if a blood sample could not be obtained during their D6 appointment, the location of which was dependent on individual circumstances. Finally, some nurses were required to see patients at an additional local surgery in order to meet cluster size requirements. While some researchers argue that 'true' fidelity to the protocol is necessary (Szulanski & Winter, 2002) in a real world setting a mixed fidelity-adaptation approach is necessary in order to account for site-specific circumstances. However, it is possible that patients may have felt less motivated to participate in D6 if they were required to make extra appointments or to attend the surgery at inconvenient times. It is also possible that nurses who were required to attend 2 surgeries felt additional burden.

Conducting a pilot study, although time consuming and expensive, may have avoided some of these problems.

Conclusion

This chapter shows that while the theoretical construct of fidelity of psychological interventions remains relatively clear, there is no consensus on how to measure it. The gold standard for measuring treatment fidelity appears to be objective ratings of audiotaped sessions, rated using a valid fidelity scale.

We applied this method to the D6 study and found that D6 nurses achieved minimum competency in most D6 skills, asking more open questions and fewer reflections in relation to questions during D6 consultations than control group nurses. They also had significantly higher BECCI practitioner scores. However, while statistically significant in comparison to the control group the absolute scores were not clinically significantly different.

This suboptimal fidelity may explain why the D6 intervention returned a null finding; the patients did not receive a sufficient level of intervention. There are many possible explanations for this, including patient and nurse factors. In the next chapter nurse factors will be explored.

Chapter 7: Psychological Skills Training to Support Diabetes Self-Management: Qualitative Assessment of Nurses' Experiences.

Chapter Summary

In the previous chapter we learnt that fidelity of the D6 RCT was suboptimal and the intervention was not implemented as intended. This may be why the main D6 RCT returned non-significant findings. Some potential explanations for this poor fidelity were posited including nurse and patient factors. This chapter will qualitatively explore the nurse experience of participating in D6.

This chapter reports on a study designed to measure the provider experience component of the process evaluation of D6. Three key themes emerged from the qualitative data including (i) positive and negative impact of D6 on nurses' practice (ii) overstepping professional boundaries and (iii) concerns about degree of support from physicians at participating practices. These themes revealed barriers and facilitators to nurses' participation in D6 and their perceived mechanisms of the D6 intervention, including transferring responsibility of T2D care to the patient and the benefits of extra time spent with them. The strengths and limitations of the study design and their potential impact on outcome are discussed.

Background

The management and organisation of care for people with T2D and other long-term conditions has changed significantly within the last 15 years. Since the introduction of the GP contracts of 1990 and 2004, primary care professionals in the UK such as GPs and practice nurses are required to take significant responsibility for disease management with support from specialist services when necessary (Roland, 2007) (NHS Employers, 2004).

The evidence for efficacy of specific psychological treatments such as MI as tools to support patients' self-management is growing, and their use becoming more

widespread. (Lloyd, Gill, & Stone, 2013) (Ciechanowski, Katon, & Russo, 2000b; Peyrot et al., 2005b). However, there is a shortage of nurses who are specialists in psychology and behaviour change management to deliver these interventions (Katon, Von Korff, Lin, & Simon, 2001; Trude, 2003), and expert mental health providers are costly, scarce and rarely have specialist diabetes knowledge. There is therefore a skills gap, which if closed would have significant long-term benefits for patients.

If existing general practice staff can be trained to deliver psychological therapies effectively, they may provide a cost effective solution to this problem (Winkley, Ismail, Landau, & Eisler, 2006). For example, a 'nurse-coaching intervention' which employed behavioural change strategies for women with T2D was effective in improving diet and exercise behaviours and reducing diabetes related distress (Whittemore, Melkus, Sullivan, & Grey, 2004). The prior experience of the nurse coaches is not described in this study, but there is evidence that diabetes specialist nurses can be trained to deliver MI and CBT and these are associated with significant improvements in glycaemic control in people with T1D (Ismail et al., 2008b). Diabetes nurses have been trained to deliver diabetes-specific therapy while maintaining psychological treatment fidelity (Maissi, 2011) and primary care nurses have been trained successfully to use motivational techniques to improve oral medication adherence in people with T2D (Hardeman et al., 2014). An intervention incorporating treatment delivered by primary care nurses could be integrated into a Stepped Care Model, in which the 'least restrictive' currently available treatment is recommended, referring to the amount of specialist intervention required (Bower & Gilbody, 2005).

Data on nurses' attitudes towards delivering psychological techniques is lacking, although some studies suggest that they may experience discomfort when dealing with mental health problems such as depression as part of their general practice (Naji et al., 2004). Further studies suggest that practice nurses may lack confidence in their ability to manage mental health problems (Byng, Weaver, & Bury, 2002). In an RCT comparing 2 practice nurse delivered psychological treatments with GP treatment as usual for Chronic Fatigue Syndrome (CFS), 3 nurses delivered either a programme of 'pragmatic rehabilitation' encompassing principles of CBT and Graded Exercise Therapy (GET) or a programme of 'supportive listening' (a form of non-directive

counselling) to a sample of 296 CFS patients in the UK. Each intervention was delivered in parallel over 18 weeks with 5 face to face home visits interspersed with 5 telephone sessions. Patients receiving pragmatic rehabilitation showed short term improvements in fatigue compared with GP treatment as usual but these improvements were not sustained at 1 year follow up. No statistically significant differences were found for patients in the supportive listening group versus GP care as usual (Wearden et al., 2006). A qualitative study exploring the experiences of the practice nurses delivering the intervention found 4 themes (i) being a novice therapist (ii) engaging patients in the therapeutic model (iii) dealing with emotions and (iv) complexity of primary care. While the nurses were highly experienced primary care nurses, they found the novel role of therapist challenging as they had a relatively limited range of therapeutic skills to draw upon and were required to learn new boundaries. They also felt challenged and scrutinised by 'expert patients' with high levels of knowledge about CFS. Nurses also experienced difficulties in managing patients' resistance to treatment, and expressed concerns about the short treatment period, which they felt opened up a 'can of worms'. Finally, nurses felt overwhelmed by the complexity of patients' comorbidities and social circumstances. Nurses also reported positive effects of the intervention, including the development of strategies for managing tensions such as 'validating patients' illness experiences', flexibility with arranging sessions, emotional support from peers and regular supervision from an experienced therapist. The challenges faced by practice nurses in this study relating to role adjustment, complexity of cases and organisational context may partly explain the non-significant findings of the main RCT, as nurses may have lacked confidence to implement therapies to protocol (Peters et al., 2011).

In environments where specialist healthcare resources are particularly limited, such as low and middle-income countries, studies have found that non-specialist mental health workers trained to deliver psychological therapies experience a number of *barriers and facilitators* to the implementation of an intervention. For example one qualitative study investigated non-specialist healthcare providers' views on participating in the Programme for Improving Mental Healthcare (PRIME) study, which generated evidence on the implementation and scaling up of integrated care packages for priority mental health problems in countries including Ethiopia, India, Nepal, South Africa, and Uganda. Participants reported benefits of the intervention

including increased access to services, money and time, and the opportunity to integrate existing support networks, such as traditional healers in the community. However, they also reported challenges, including social stigma, increased workload, transportation issues and lack of on-going supervision from an experienced clinician (Mendenhall et al., 2014). A systematic review by the same research group (PRIME) found common themes emerge when investigating the impact of training non-specialist healthcare providers to perform tasks usually required of specialists. They reviewed studies from 14 low and middle income countries and found a scarcity of individuals who were suitable to perform tasks, variable self-perceived competency across non-specialist healthcare providers, a lack of training and subsequent supervision and high burden of increased workload (Padmanathan & De Silva, 2013). These consistently emerging themes are important considerations for researchers conducting tests of interventions delivered by non-specialists, as they may affect quality of intervention delivery.

The D6 Study described in Chapter 5 was an RCT testing whether general practice nurses can be trained to deliver specialist psychological therapies.

Aims

The aims of the current study are (i) to explore the process evaluation component of *Provider Experience* and (ii) to identify *Barriers and Facilitators* to nurses' participation in D6.

Methods

All 23 nurses who participated in the D6 study were invited to interview. Nurses in the intervention arm had received training according to the D6 manual, which had been delivered by a clinical psychologist over 12 weekly sessions. During the intervention delivery period, nurses in the intervention arm had had monthly group supervision sessions with the psychologist. Nurses in both arms had attended an introductory session, which reviewed current NICE guidelines and psychological therapies for diabetes. Nurses in both arms aimed to deliver 12 x 30 minute

individualised, audiotaped patient sessions over 12 months. The intervention comprised techniques drawn from MI and CBT.

Semi-structured interviews were conducted with individual nurses at their place of work. They took place after their participation in D6 had ended. The topic guide was developed using observational data collected during monthly supervision sessions with intervention nurses and an interview with a member of the research team who recruited the nurses into the study (2nd supervisor KW). Two interview topic guides (one for nurses allocated to the intervention arm and one for nurses allocated to attention control) were developed in response to this preliminary research, and included (see Appendix IV): experiences of D6 training; supervision and support (intervention group only); the D6 intervention (intervention group only); self-awareness; interaction with study patients; and views about psychological research.

The 2 interview topic guides consisted of open questions to elicit free responses, with follow up questions for prompting and probing. The interview was piloted with 2 nurses (1 intervention, 1 control), to assess relevance and comprehension of topic guides. No changes to the interview schedules were necessary and the data were included in the main study. Fifteen of the 16 interviews were audio recorded and transcribed verbatim. One interview was not recorded at the request of the nurse. In this instance the researcher took notes throughout the interview, which were checked and approved by the nurse concerned.

A thematic analysis approach was used to analyse the data, allowing the researcher to compare and contrast themes across participants. The specific method used was framework analysis (Ritchie, 2011). Framework analysis was developed for use in large scale social policy research before gaining popularity as a method for analysing medical and healthcare research data (Ritchie, 2011). It is defined by the output of a 'matrix,' which uses rows and columns to organise data by case (case = interviewee). The matrix allows data to be compared and contrasted across and within individual cases so that broad themes may be identified without losing individual context.

The stages of framework analysis were as follows:

(i) Transcription: interviews were transcribed verbatim by a professional independent transcription service with the exception of 1 interview, which was transcribed by the researcher.

(ii) Familiarisation: the researcher read all transcripts and listened to sections of the recording where context was unclear and tone of voice important. Brief notes were made on potential points of interest.

(iii) Coding: The researcher coded all transcripts, highlighting relevant sections of text, assigning coding labels (themes) and making relevant notes.

(iv) Developing and applying a working analytical framework: when the researcher had completed coding, themes were discussed with supervisors until consensus was reached. A set of codes with definitions was produced, forming an analytical framework. An independent researcher coded a sample (n = 3) of interviews to assess inter-rater reliability. The coding structure did not require amendment.

(v) Charting data into the framework matrix: The data were entered into and managed using the qualitative computer software program Nvivo 11 (QSR, 2016). The matrix comprised 1 row per participant and 1 column per code.

(vi) Interpreting the data: the framework matrix was reviewed and connections made between participants and themes. Any discrepancies were discussed with supervisors. Themes were explored with the question 'how does this relate to the quality of implementation of the intervention?' in mind.

Rationale for Employing Framework Analysis

There are a number of advantages to employing framework analysis which promote rigour and transparency, including (i) summarising the data, making it practical to discuss individual cases within the research team without the need for researchers to read entire transcripts (ii) charting the data which requires the researcher to closely examine each participant's subjective experience prior to interpretation (iii) the visual

structure of the matrix is easy to follow (iv) the method as a whole is highly systematic and clearly structured (v) it is not aligned with a particular theoretical approach or epistemological viewpoint meaning it can be used for inductive or deductive analysis e.g. the researcher may use theoretical constructs to deductively, or use an inductive approach to identify theme within the data which are then discussed using theories from the literature (Gale, Heath, Cameron, Rashid, & Redwood, 2013).

Reflexivity in Qualitative Research

Reflexivity in qualitative research refers to a method of attending researcher effects at every stage of the research process in order to improve validity (Malterud, 2001). The researcher reflects on the way research is carried out and understands how the process of undertaking research has potentially affected outcomes. The background and position of the researcher will affect their angle of investigation, selection of methods, interpretation of findings and conclusions drawn. As the researcher plays such a crucial role in collection, analysis and interpretation of data in qualitative research, it is essential that we understand their position, perspective, beliefs and values (Koch & Harrington, 1998). These factors will be discussed as strengths and limitations of this study.

Results

Of 23 eligible nurses, 7 did not respond to repeated (n = 3) invitations to participate. Sixteen nurses therefore participated (9 randomised to the intervention and 7 to the control group). All were female (n = 16), with a mean age of 50 (SD = 7.17) years. The distribution of ethnicity was white 50% (n = 8), black 31% (n = 5) and Asian/other 19% (n = 3). Nurses worked in GP surgeries in 4 South London boroughs. The distribution of nurse by borough was 44% (n = 7), 25% (n = 4), 19% (n = 3) and 13 % (n = 2). Nurses were interviewed as soon as possible after the intervention period had ended with interviews conducted at their individual GP practices after clinics had finished for the day.

Of the intervention group nurses interviewed, 11% had previously received a training module in psychological therapies as part of a degree course (n =1), 11% had received training in MI as part of a previous role in smoking cessation (n =1), 11% had received some training as part of a nursing qualification (n=1) and 67% (n=6) had not received any previous training in psychological therapies. Of the control group nurses interviewed, 14% had received some training in psychological therapies as part of a degree course (n=1), 29% had received 1 day or less of training in MI (n=2), 14% (n=1) had received some MI training as part of the Co-creating Health program (Wallace, 2012), 14% had received some MI training as part of a previous role in smoking cessation (n=1) and 43% had not received any training in psychological therapies (n=3).

Themes

Three key themes were identified in relation to the nurses' experiences of participating in the D6 study (i) positive and negative impact of D6, (ii) professional boundaries and (iii) support. There were sub-themes within each of these main themes.

1. Positive and Negative Impact of D6

Transferring Responsibility to the Patient

Of the 16 nurses interviewed, 6 (of 9) nurses in the intervention group felt that D6 had a positive impact in the sense that the D6 skills helped to transfer some responsibility of diabetes management back to the patient. They reported that patients felt empowered.

> *"...with the motivational interviewing... it's going to ...give them that control, and want to change, and this is what happened." (PTP14L, Asian/Other, aged 46-55 years, intervention group)*

One nurse felt that this emphasis on patient self-regulation had reduced her own sense of burden.

"I was psychologically and physically tired because I was taking on too much, I was carrying the patient's responsibility and so the positive for me...is now my consultations are less stressful..." (PTP06L, Black, aged 46-55 years, intervention group)

One control group nurse felt that the extra time with patients mandated by the study protocol for both intervention and control arms played a part in encouraging patients to change their behaviour.

"If you're seeing somebody really very regularly...the patient will have to keep saying to me 'oh no, actually I'm still not doing my exercise, I'm still not doing that', it really puts the onus on them." (PTP02L, White British, aged 46-55 years, control group)

Transferable Skills

Five nurses from the intervention group felt they had gained valuable skills from the D6 training, which could be used with other patient groups.

"...what's so good about the D6... it's so versatile, you can use the same skill in many areas, like sexual health...I'm always praising the D6 for what it's done for me, as a clinician." (PTP14L, Asian/Other, aged 46-55 years, intervention group)"

"I also had a group of patients that were very poorly controlled and had very complex problems...and I was seeing that group alongside my D6 with the same frequency... I've been able to improve the control from a big percentage of our patients." (PTP06L, Black, aged 46-55 years, intervention group)

Time Luxury

Three nurses from the intervention group and five nurses in the control group reported feeling that the length of D6 appointments was a luxury. D6 appointments were 30

minutes long for the intervention and control group. They felt able to address wider, lifestyle-related concerns.

> *"I think the length of the appointments most nurses would say reinforce what we always knew, that we need more than ten minutes." (PTP06L, Black, aged 46-55 years, intervention group)*

> *"... It gives us...that opportunity to actually listen to the patients...because, like I said, normal check... we don't listen." (PTP15W, Black, aged 56-60 years, intervention group)*

> *"It gave you the time to actually sit with a patient... address their concerns, and try to relieve their fears and anxiety." (PTP05S, Black, aged 46-55 years, control group)*

> *"...it's a luxury having thirty minute appointments for people, huge luxury."(PTP02L, White, aged 46-55 years, control group)*

> *"I was able to just do a bit more touchy-feely you know stuff rather than just in out...adjust your medication".(PTP09L, White, aged 46-55 years, control group)*

Patient Barriers

Of the 16 nurses interviewed, 13 (8 intervention, 5 control) described 'patient barriers' as a negative aspect of D6.

Ten nurses (6 intervention, 4 control) experienced problems with patient non-attendance and lack of willing to commit to D-6 appointments.

> *"When it actually came to making the commitment they weren't prepared to do it." (PTP13L, White, aged 46-55 years, control group)*

"I would say the chaotic ones who could have really done with the help tended to either…not attend follow-up or…just drop off." (PTP09L, White, aged 46-55 years, control group)

Four of these nurses felt that some patients did not consider diabetes self-management to be a priority.

"…not everybody wants to make changes in life, people are happy just plodding along…" (PTP04W, Asian/Other, aged 30-45 years, intervention group)

"…it's not a priority to them, there's too many other things going on." (PTP13L, White, aged 46-55 years, control group)

Four nurses felt that lack of patient engagement was a problem**.**

"...some patients they don't come out with anything so...I'm not supposed to tell the answers and where I used to tell the answers all our life as nurses" (PTP07S, Black, aged 30-45 years, intervention group)

"Most of them, they don't even believe they have diabetes." (PTP16L Black, aged 30-45 years, intervention group)

Three nurses suggested that low IQ may be a barrier for some patients.

"If someone has a low IQ it is very hard to get them to participate." (PTP04W, Asian/Other, aged 30-45 years, intervention group)

Time Management Barriers

Time management issues were raised as a barrier for 8 of the nurses interviewed (4 intervention and 4 control group). Three nurses talked about the extra work created by D-6, and how they found it difficult to manage the study in addition to their already heavy workloads.

"...my workload is so heavy and fast moving I seldomly have the luxury of reflection time...when you are studying a new skill and working it's fine when you're in the classroom, but...if we weren't getting those frequent [supervision] meetings it would not have been that easy." (PTP06L, Black, aged 46-55 years, intervention group)

Five nurses expressed concerns about the practicality of integrating D6 within an existing primary care service.

"...what this research is asking us is a lot...why would you want to do a research that in real life will never, ever take place or couldn't?" (PTP11S, Asian/Other, aged 46-55 years, control group)

"I knew it wouldn't work if I just tried to do it in the normal sessions...with the pressure on appointments." (PTP13L, White, aged 46-55 years, control group)

The amount of administration time involved in participating in D6 was a concern for two of the nurses interviewed. This included time spent recording patient consultations.

"because I liaise with you... it wasn't a big problem but...when we were told...that we have to write this, we have to record this...I thought it will never happen, it cannot happen." (PTP11S, Asian/Other, aged 46-55 years, control group)

Change of Pace

The D6 appointments lasted for half an hour, and four of the nurses (2 intervention, 2 control) felt the impact of a change of pace.

"Because you're seeing them so regularly it can get a little bit...awkward... when you're thinking "oh I've got to see you again in two weeks and I've got to think of a plan of what we can discuss." (PTP08L, White, aged 56-60, control group)

"Our consultations are ten minutes so if you haven't got what [you need] then you have to make another appointment...the patients...weren't used to that at all and it was a bit uncomfortable..." (PTP01L, White, aged 56-60 years, intervention group)

One nurse felt guilty about conducting D6 appointments in regular surgery hours and expressed concerns that colleagues may have felt she was doing less work than others.

"I did feel that actually it looked like I could have been doing other things... especially when you've got a really busy practice." (PTP02L, White, aged 46-55 years, control group)

2. Professional Boundaries

Over-Stepping Role

One control and 3 intervention group nurses expressed concerns about over-stepping their role when delivering the D6 intervention.

"They didn't use it for diabetes, they used it to...unload their problems on me and I didn't know how to deal with these problems because I am not a psychologist, I'm only a nurse." (PTP04W, Asian/Other, aged 30-45 years, intervention group)

"I would keep reflecting back to them and doing reflective listening but because I'm not trained in psychological therapies I was actually quite concerned at some points...that I might be over stepping my role in terms of my competence." (PTP12S, White, aged 56-60 years, control group)

Harassing the Patient

Having experienced problems with patient attendance throughout the study, one control group and three intervention group nurses felt that they were harassing patients to come to appointments.

"The time that you spend trying to get patients in... you almost feel like you are kind of bothering them." (PTP05S, Black, aged 46-55 years, control group)

"That was horrendous...there were so many phone calls...and when you get them they will say they'll come and then they don't." (PTP04W, Asian/Other, aged 30-45 years, intervention group)

Role Adjustment

Four nurses in the intervention group and 2 in the control talked about the professional role adjustment that was required by them to participate in the D6 Study. They felt they had to change the style of their consultations.

"...I didn't feel confident and was thinking, what should I say next, what should I do next." (PTP04W, Asian/Other, aged 30-45 years, intervention group)

"...thinking about what the patient's saying and thinking 'oh my God, I've got to use this...skill to get this information out of them" (PTP03L, White, aged 30-45 years, intervention group)

3. Support

Support from participating surgery

The need for support from the practice physician was raised as an issue by seven of the nurses (4 intervention, 3 control).

Three of the nurses talked about the money that had been paid to the practice as an incentive to participate in D6 and felt it was unfair they had not received any of it themselves.

"I don't know if any nurses who [are] taking part were paid... although we took ...the time... for the patients but none of us got...even a £10 bonus." (PTP11S, Asian/Other, aged 46-55 years, control group)"

The above participant went on to say that she was surprised to receive little support to participate in the study, considering the financial benefit for the practice.

> *"I find that although I did take part it was up to me to convince them to let me go [and participate in D6] even though there was monetary incentive for them." (PTP11S, Asian/Other, aged 46-55 years, control group)"*

Three other nurses expressed feelings that they were undervalued.

> *"I had to fight, I said "okay I'm going to leave the D6... you're the ones who get the money for D6. I'm not getting anything...I would like to help my patients but if you have got any problems with me doing the D6 then I will leave ...and help with open surgery' ...they were not that supportive really." (PTP07S, Black, aged 30-45 years, intervention group)"*

> *"They were very pleased with the money but...that was about it really, the support wasn't really there..." (PTP01L, White, aged 56-60 years, intervention group)"*

> *"It's just another affront of how doctors think... they could take the services and the expertise of nurses and use it to their advantage with no recognition...." (PTP06L, Black, aged 46-55 years, intervention group)"*

The need for extra support from other teams such as administration and IT was raised by four of the nurses.

> *"I think if I was to do this again I think we would need the whole practice team [to help] and [receive] input from different departments." (PTP05S, Black, aged 46-55 years, control group)*

> *"The good thing is we had an admin person who was specifically there for diabetes, so she was...willing to help and support..." (PTP09L, White, 46-55 years, control group)*

Supervision

Four of the intervention group nurses highlighted the importance of supervision from the psychologist at King's.

> *"it give you that opportunity to offload and you get input from everybody...and it also reinforces, okay right, so I was on the right track...I'm really going to miss that." (PTP06L, Asian/Other, aged 46-55 years, intervention group)*

> *"...we discuss our difficult patients...and we get some suggestions of how to deal with those that are not getting on well. So I think... it's helping a lot going to those sessions" (PTP07S, Black, aged 30-45 years, intervention group)*

Two of the nurses felt however that more supervision would have been helpful.

> *"...perhaps because I didn't have any psychology background a bit more input would have helped really." (PTP04W, Asian/Other, aged 30-45 years, intervention group)*

Discussion

The aim of this study was to explore primary care nurses' experience of psychological skills training as part of the D6 Study. Three main themes emerged from the data, (i) positive and negative impact of D6, (ii) professional boundaries and (iii) need for support. There were two sub-themes ('transferrable skills' and 'supervision') mentioned only by nurses in the intervention group, as these nurses were the only group to receive D6 skills training and supervision. Two sub-themes ('time management barriers' and 'change of pace') were mentioned equally by intervention and control group nurses. These two groups would have faced similar challenges in fitting D6 appointments into their schedules due to the attention control design of the trial. Remaining sub-themes emerged from both intervention and control group data.

Nurses in both groups cited patient barriers as the most significant obstacle preventing them from implementing D6 according to protocol, including lack of attendance at appointments, lack of willingness to commit to scheduled appointments and patients not prioritising diabetes self-management. This may be explained by the fact that the D6 sample was drawn from a population with poor glycaemic control who are likely to have lower levels of commitment to self-management and poorer records of attendance at their primary care practice. Nurses in both groups also raised concerns about professional boundaries; however more nurses in the intervention group were concerned that they were harassing patients to come to appointments and it may be that nurses in this arm felt more responsibility to ensure patient attendance at appointments having received the D6 training. Some nurses in the intervention arm also felt that they were over-stepping their professional role when using MI skills or dealing with emotive consultations, as they were not qualified as psychologists. This is consistent with studies showing that practice nurses fear becoming involved in consultations about mental health as they feel inadequately equipped to deal with any psychological problems that may arise (Gray et al., 1999; Nolan, Murray, & Dallender, 1999). This is also consistent with the finding that nurses in both groups felt they needed to adjust their role in order to facilitate the use of D6 skills (intervention group), or to fill longer appointment times (control group).

Nurses in both groups felt that they had been under-supported by their practice during their participation in D6, and some felt that they were entitled to financial compensation. The need for input from other practice departments was highlighted, and it is worth noting that nurses required significant support from the D6 research team. This finding is consistent with studies which have found that non specialist healthcare providers trained to deliver specialist therapies require significant support from supervisors (Padmanathan & De Silva, 2013).

Strengths and Limitations

A strength of this study is that it was developed a priori as part of the process evaluation of the D6 Study. The results of the RCT were not known at the time of

data collection or analysis, so there is less bias in nurse or researcher reporting. A systematic, established approach to data analysis was used and inter-reliability analysis conducted by an independent researcher. However framework analysis is time consuming and resource intensive, particularly within the context of a PhD. Qualitative analysis generates rich data, offering a deep level of understanding of the phenomenon under investigation. However, it requires significant time to collect and analyse and requires the researcher to develop skills in coding and thematic interpretation. Data interpretation is subjective and reflexivity important in order to minimise bias.

One approach to further minimise bias would be for the researcher to keep a reflexive research diary to record reflections on each stage of research design and data collection that may have methodological and theoretical implications. For example, a research diary of the semi-structured interview process would involve recording the interview experience, covering practical issues in addition to observations of the interview as a social experience. It may also involve reflections on the success (or otherwise) of the interview and note any emotional observations (e.g. did the researcher feel irritated). Observations noted in a reflexive diary may have led to extra vigilance during triangulation. For example, in a report of a reflexive diary used during a PhD focusing on management research, the author concluded that reflexive diarising had prompted her to consider supplementary methods of analysis, fuelled theoretical discussions and impacted analytical decisions (Nadin & Cassell, 2006).

Researcher effects on collection, analysis and interpretation of data are a crucial consideration in qualitative research. A limitation of this study is that the researcher held the position of D6 research assistant for the duration of the intervention period and had regular prior contact with 14/16 nurses. Nurses who were in contact with the researcher for the duration of the intervention (and to a lesser extent those who weren't) may have felt unable to fully disclose their feelings about D6 due to a social desirability bias (Van de Mortel, 2008). They may have feared disappointing or offending the researcher and by extension the research team. Nurses required significant supervision from Research Assistants for the duration of the D6 intervention and it is possible that the researcher's knowledge of challenges faced by nurses framed the design of interview schedules, the conduct of the interviews,

analysis of data and interpretation of results. Although triangulation was used in order to minimise bias in analysis of data, significant potential for bias remains. A potential solution to this problem could have been the use of multiple, independent interviewers, although limited resources prohibited this.

A further limitation is that the sample of nurses was not optimal. Seven nurses did not respond to repeated invitations to participate (2 intervention and 5 control group), representing a significant portion of 'missed' data. The data are also not transferable (a concept synonymous with generalisability) to different healthcare professional populations or contexts. However, the sampling in qualitative research is not designed to be representative of a wider population but purposive to capture the diversity around a phenomenon. Every effort should be made to provide 'thick description', a term coined by Lincoln and Guba (Guba & Lincoln, 1985) to describe a 'technique in which a qualitative researcher provides a robust and detailed account of their experiences during data collection'. Details of the research setting should be described, including time and place of interviews and implicit biases, which may affect responses. The reader may then construct an impression of the research environment, which allows them to more accurately judge the transferability of results (Houghton, Casey, Shaw, & Murphy, 2013).

Conclusion

This qualitative study found that primary care nurses trained in psychological skills perceived that those skills were valuable and transferable in a primary care setting, despite the existence of time management and patient barriers to attendance. The utilisation of psychological skills within this setting requires significant role adjustment for nurses, which may be aided by additional support from physicians, the wider practice team and a qualified psychologist. As expectations rise for more management of long-term conditions in primary care, its staff will need more skills in behaviour change. The findings of this study indicate that nurses working in primary care require significant support from other practice team members and a qualified psychologist in order to adjust their consultation style and schedule within a busy

general practice. When this support is received however, they can feel more capable and competent to deliver a psychological therapy.

Qualitative evaluation of psychological interventions may help to reveal mechanisms which hinder or promote implementation of the intervention according to protocol. Future research may involve incorporating qualitative studies into the analysis plan of RCTs of similar interventions in different settings and with different populations to see if similar findings are identified.

Chapter 8: Patients' Experiences of Participating in a Randomised Controlled Trial of a Psychological Therapy Designed to Improve Sub-Optimal Glycaemic Control In Type 2 Diabetes: A Qualitative Study

Chapter Summary

In the previous chapter we learnt that although nurses felt that psychological skills training can have a positive impact on patient care, significant role adjustment is required, and appropriate support strategies must be implemented.

This chapter explores patients' experiences of participating in D6. The rationale for collecting patient feedback when conducting a process evaluation and the different methods that can be used will be described. Using individual qualitative interview methods, the main finding was that patients experienced a number of barriers and facilitators to their participation in D6. These findings are discussed in an attempt to further understand the *Barriers and Facilitators* in delivering psychological care to support self-management in T2D.

Background

Psychological Barriers to Diabetes Self Care

Persistent sub optimal glycaemic control of T2D remains a significant problem, despite the development of evidence based pharmacological, educational and lifestyle interventions (King et al., 1999), with T2D increasingly recognised as a huge psychological burden for the patient due to the level of self-management required (Jallinoja et al., 2007). People with T2D are expected to take significant responsibility for disease management through the implementation of lifestyle adjustments, which may include dietary changes, increases in physical activity, improved concordance with oral hypoglycaemic agents and self-administration of insulin injections, self-

monitoring of blood glucose and bodily changes, all of which may reduce the rate of disease progression (Winkley et al., 2016). However, many people find these adjustments difficult despite support from healthcare providers, and many have psychological barriers to implementing and adopting these behaviours (Snoek et al., 2011).

The psychological barriers to diabetes self-management are numerous and can include mood disturbances (Lustman et al., 1997), disordered eating (Herpertz et al., 1998) and diabetes-specific fears. People with T2D are twice as likely to suffer from depression than the general population (Ali, Stone, Peters, Davies, & Khunti, 2006) and depression is associated with lower adherence to oral hypoglycaemic, antihypertensive, and lipid-lowering medications (Lin et al., 2004) and lower adherence to self-care behaviours such as physical activity and diet (Ciechanowski et al., 2000a). Depression is also associated with an increased risk for diabetes complications such as diabetic retinopathy, nephropathy, neuropathy and macrovascular complications and sexual dysfunction (De Groot et al., 2001). Rates of anxiety in patients with diabetes may also be higher than those typically reported in the general population (Peyrot et al., 2005a), and the presence of anxiety is associated with increased prevalence of diabetes-related complications (Wu et al., 2011). One study found that diabetes-specific distress mediated the relationship between depression and glycaemic control in patients with both T1D and T2D (Van Bastelaar et al., 2010).

Psychological barriers to insulin injections also represent a major problem. Insulin is safe (although there are risks to its use), effective and the most potent drug available with the potential to achieve optimal glycaemic targets (NICE, 2015). However, it is often not introduced early or to optimal therapeutic targets to benefit patients in terms of improving glycaemic control and reducing risk of diabetes complications (Brunton, Davis, & Renda, 2006). Fears around insulin can represent significant psychological barriers, for example one study exploring patient attitudes towards insulin found that fears and negative emotions related to insulin were much more commonly discussed than positive ones, and included worries about the pain and hassle of injecting insulin, fear of hypoglycaemia and concerns that diabetes had progressed to a more serious phase (Hunt, Valenzuela, & Pugh, 1997). Another study reported that patients did not

perceive their illness as serious enough to warrant taking insulin with others worried they might become addicted to it (Nakar, Yitzhaki, Rosenberg, & Vinker, 2007). 'Psychological insulin resistance' is a term that is sometimes used, with many people reporting multiple reasons for resisting insulin use, even once prescribed. Additional reasons for this include fear that insulin use will restrict lifestyle, low self-efficacy with regards to administering insulin, fears that insulin will harm the body and fears that once insulin has been started, it cannot be stopped (Polonsky et al., 2005).

Disordered eating may also be a barrier to diabetes self-management, with abnormalities of eating attitudes and behaviour associated with impaired metabolic control (Mannucci et al., 2002). Binge eating disorder in particular may be an independent risk factor for T2D (Herpertz et al., 2000; Kenardy et al., 2001) and has been shown to precede T2D (Herpertz et al., 1998), particularly in younger and African American populations (Meneghini, Spadola, & Florez, 2006). In addition, clinical and subclinical levels of binge eating have been associated with greater incidence of depressive symptoms and impaired quality of life in the T2D population (Wilfley, 2011).

One of the most significant psychological barriers to the self-management of T2D is that people lack motivation or are unwilling to take responsibility for self-management of their disease. They may be unable to accept the chronic nature of T2D and come to terms with the significant lifestyle adjustments necessary in order to manage it effectively (Brown et al., 2002). In addition, people with T2D may experience low levels of self-efficacy with respect to their abilities to manage their diabetes effectively, with a perception that their fate is out of their hands (Glasgow, Toobert, & Gillette, 2001).

A large study involving 3649 people with T2D from 62 general practices in England found a significant relationship between psychological barriers to self-care and diabetes related complications of the eyes, feet, legs, kidneys and heart, reinforcing the need for holistic diabetes care (Sina, Graffy, & Simmons, 2018).

Addressing Psychological Barriers to Diabetes Self-care

Addressing such psychological barriers may represent a cost effective method of improving glycaemic control in this population, avoiding the need for further pharmacological intervention. As summarised in Chapter 4, there have been several systematic reviews of RCTs of psychological interventions to improve glycaemic control which together suggest that psychological interventions may be associated with a small improvement in glycaemic control but there were methodological limitations, namely small sample size and poorly described interventions (Alam et al., 2009; Ismail et al.). More recent reviews have used broader terminology when identifying studies, encompassing educational interventions (which may have a psychological component) and other psychosocial programmes. These studies have found small effect sizes however and are again limited by methodological weaknesses (Harkness et al., 2010; Heinrich, Schaper, & de Vries, 2015; Schellenberg, Dryden, Vandermeer, Ha, & Korownyk, 2013).

Evaluating Psychological Therapies Delivered in Primary Care

In order to fully evaluate the impact of psychological therapies delivered in primary care, it is necessary to evaluate their delivery from the patients' perspective. Patients' values about psychological treatments have rarely been studied but insights into patients' perspectives on diabetes self-management in a general practice setting can give insight into how treatments are perceived and valued, and how they are best delivered in order to make change. For example, one study synthesised qualitative research on lay experiences of diabetes and diabetes care, reviewing 10 qualitative studies of adult patients' perspectives of diabetes care in the UK. The authors used meta-ethnographic methods to synthesise the research, finding that patients feel 'the need to be permitted to care for themselves' and need support from the care team in order to accomplish this, but feel they do not receive that support when their control is sub-optimal, i.e. they do not receive it when they need it most (Wikblad, 1991). Another qualitative study explored UK primary care patients' perspectives on foot complications in T2D using one on one interviews, revealing that some patients do not take advice on self-care due to communication problems with health professionals

(Gale, Vedhara, Searle, Kemple, & Campbell, 2008). A qualitative interview study exploring 18 T2D patients' perspectives of blood glucose self-monitoring found that self-monitoring decreased over time as patients felt that GPs perceived lack of interest in readings as meaning they were not worth continuing. Only 3 patients were self-monitoring as advised in their initial diabetes education at 12-month follow up (Peel, Douglas, & Lawton, 2007). Exploring patients' views can therefore often tell us about the 'how and why' of their behaviour, revealing reasons behind the incongruence between providers' and patients' views of self-management (Cohen, Tripp-Reimer, Smith, Sorofman, & Lively, 1994).

Aim

The aims of the current study are (i) to explore the process evaluation component of *Participant Experience* and (ii) to identify *Barriers and Facilitators* to patients' participation in D6.

Methods

The Current Study

A stratified convenience sample of patients who participated in D6 was invited to interview. A sampling matrix was stratified by demographic characteristics and treatment arm. Table 8.1 shows the original sampling strategy.

Table 8.1: Original Sampling Matrix		
Sample Characteristic	Intervention	Control
Age		
30-50 years	10-15	10-15
51-82 years	10-15	10-15
Ethnicity		
White	5-8	5-8
Black	5-8	5-8
Asian	5-8	5-8
Other	5-8	5-8
Gender		
Male	10-15	10-15
Female	10-15	10-15
Borough		
Lewisham	5-8	5-8
Lambeth	5-8	5-8
Southwark	5-8	5-8
Wandsworth	5-8	5-8

Semi-structured interviews were conducted by the D6 researcher (PhD candidate) at each patient's GP surgery after completing their final D6 follow up appointment. Time between final follow up appointment and interview ranged from 21-82 days, with a mean interim duration of 48 days. The topic guide was developed based on the observations and experiences of the D6 researcher (PhD candidate) who recruited patients into the study and was in contact with many of them for the duration of the intervention. Observations were collected in note format during the study. Observations were noted based on conversations over the phone and in person with patients who were participating in D6 and concerned reasons why patients were not able to attend D6 appointments; the researcher's own experience and nurses' experiences of frequency of D6 appointments and how their timing might affect patients; feedback from nurses and patients on content of sessions and researchers'

instincts and curiosity in relation to patients' views on psychological treatments. An interview topic guide was developed covering: views on the timetable of the study and its sessions; barriers to attending; views on the treatment received and views on psychological research in general. These guides were discussed within the research team and refined until consensus reached. The topic guides consisted of open questions to elicit free responses, with follow up questions for prompting and probing. The interview guide is included in Appendix IV.

The interview was piloted with 2 patients (1 intervention, 1 control) to assess comprehension and relevance of questions. No changes to the schedule were necessary and the data were included in the main study. All 18 interviews were recorded and transcribed verbatim.

A thematic analysis approach was used to analyse the data, allowing the researcher to compare and contrast themes across participants. The specific method used was framework analysis (Ritchie, 2011). Framework analysis was developed for use in large scale social policy research before gaining popularity as a method for analysing medical and healthcare research data (Ritchie, 2011). It is defined by the output of a 'matrix,' which uses rows and columns to organise data by case (case = interviewee). The matrix allows data to be compared and contrasted across and within individual cases so that broad themes may be identified without losing individual context.

The stages of framework analysis were as follows:

(i) Transcription: interviews were transcribed verbatim by a professional independent transcription service with the exception of 2 interviews, which were transcribed by the researcher.

(ii) Familiarisation: the researcher read all transcripts and listened to sections of the recording where context was unclear and tone of voice important. Brief notes were made on potential points of interest in order to inform the next stage of analysis.

(iii) Coding: The researcher coded all transcripts, highlighting relevant sections of text, assigning coding labels (themes) and making relevant notes.

(iv) Developing and applying a working analytical framework: when the researcher had completed coding, themes were discussed with supervisors until consensus was reached. A set of codes with definitions was produced, forming an analytical framework. An independent researcher coded a sample (n = 3) of interviews to assess inter-rater reliability. The coding structure did not require amendment.

(v) Charting data into the framework matrix: The data were entered into and managed using the qualitative computer software program Nvivo 11 (QSR, 2016). The matrix comprised 1 row per participant and 1 column per code.

(vi) Interpreting the data: the framework matrix was reviewed and connections made between participants and themes. Any discrepancies were discussed with supervisors. Themes were explored with the question 'how does this relate to the quality of implementation of the intervention?' in mind.

Rationale for Employing Framework Analysis

There are a number of advantages to employing framework analysis which promote rigour and transparency, including (i) summarising the data, making it practical to discuss individual cases within the research team without the need for researchers to read entire transcripts (ii) charting the data which requires the researcher to closely examine each participant's subjective experience prior to interpretation (iii) the visual structure of the matrix is easy to follow (iv) the method as a whole is highly systematic and clearly structured (v) it is not aligned with a particular theoretical approach or epistemological viewpoint meaning it can be used for inductive or deductive analysis e.g. the researcher may use theoretical constructs to deductively, or use an inductive approach to identify theme within the data which are then discussed using theories from the literature (Gale et al., 2013).

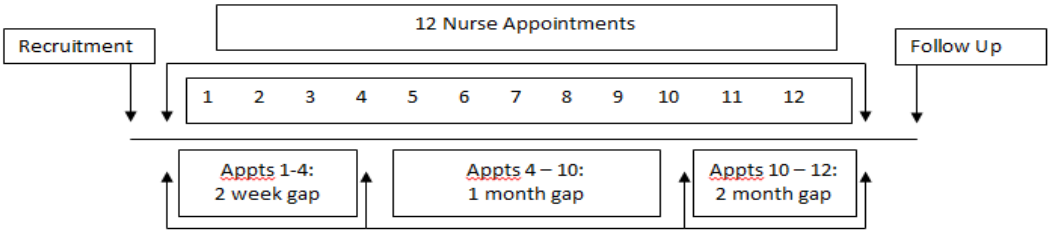
Reflexivity in Qualitative Research

Reflexivity in qualitative research refers to a method of attending researcher effects at every stage of the research process in order to improve validity (Malterud, 2001). The uses methods such as a reflexive diary to record thoughts and feelings on the way research is conducted in order to make sense of how the research process has potentially affected outcomes. The researcher's background and employment will affect their angle of investigation, selection of methodologies, interpretation of findings and conclusions drawn. It is essential that we understand the researcher's position, perspective, beliefs and values (Koch & Harrington, 1998). As Malterud notes however, 'preconceptions are not the same as bias, unless the researcher fails to mention them.' (Malterud, 2001) These factors will therefore be discussed as strengths and limitations of this study.

Results

As part of D6, nurses allocated to the intervention arm were trained in 6 psychological skills drawn from MI and CBT. Training was received through interactive training workshops and ongoing support from a clinical psychologist. Nurses were asked to practice skills learned during the training workshops by integrating them into their practice with their caseload at that time. Nurses then delivered usual care plus D6 psychological skills to patients for at least 6 face to face sessions followed by a further 6 appointments in a format agreed with the patient (e.g. either in person or over the telephone). Each session lasted 20 – 30 minutes. Time between appointments increased over the duration of the intervention, reducing in frequency. The frequency of D6 appointments is shown in Figure 8.1.

Figure 8.1: Intervention Schedule



Nurses in the attention control condition were required to deliver appointments at the same frequency and duration but without any psychological skills training.

Sample Characteristics

Of the 103 patients invited to participate in the study, 48 did not respond to repeated invitations to participate and 37 refused to participate. Eighteen patients therefore participated (11 had been randomised to the intervention and 7 to the attention control group). The sample characteristics are presented in Table 8.2.

Table 8.2: Sample Characteristics (n = 18)		
	Intervention	Control
Mean age (years)	62	55
Ethnicity (%)		
White	45.5	100
Black	45.5	
Asian/Other	9	
Borough		
Lambeth	7	2
Wandsworth	4	
Lewisham		2
Southwark		3
Employment Status		
Employed	2	3
Unemployed	1	2
Retired	8	2
Mean interview duration in minutes (SD)	41.15 (6.84)	38.65 (6.31)

Table 8.3: Sampling Matrix Showing Actual Numbers Recruited

Sample Characteristic	Intervention	Control
Age		
30-50 years	7	5
51-82 years	4	2
Ethnicity		
White	5	8
Black	5	0
Asian	1	0
Other	0	0
Gender		
Male	4	4
Female	7	3
Borough		
Lewisham	0	2
Lambeth	7	2
Southwark	0	3
Wandsworth	4	0

Table 8.4: Individual Patient Characteristics Showing Number of D6 Sessions and Interview Data (n = 18)

Patient ID	Age	Ethnicity	Number of D6 Sessions Attended	Number of Days Between Last D6 Session and Interview	Interview Duration (minutes)
001	65	White British	12	46	46.01
002	49	White British	12	61	35.36
003	45	Asian British	11	30	27.32
004	36	White	12	35	45.00
005	68	Black British	12	62	46.02
007	76	Black British	12	28	36.31
009	70	White British	12	54	38.01
010	77	Black British	9	65	36.04
011	50	White British	9	82	44.10
012	69	White	11	65	54.00
014	60	White	8	45	33.12
015	51	Black British	10	66	38.23
016	55	White British	12	21	33.02
017	63	White British	11	36	45.00
018	43	Black British	10	65	44.25
019	61	White British	12	55	46.2
020	68	White British	12	41	42.23
021	57	White Irish	10	23	33.10

Themes

The key themes identified in relation to patients' experiences of participating in D6 related to (i) content and frequency of appointments (ii) successful behaviour change and barriers to behaviour change (iii) positive and negative views about nurses and (iv) reasons for taking part.

1: Frequency and Content of Appointments

Seven patients felt they benefitted from spending extra time with their nurse during the D6 study (3 intervention, 4 control).
Three patients in the intervention group felt that the extra time available for D6 appointments was a positive aspect of their participation.

'It was a good length of time 'cos we were able to get everything in.' (PTP018, intervention group)

'We talk as well like, 'how are you?' or whatever… I would call it relaxed…' (PTP012, intervention group)

Four patients in the control group felt that the half hour appointment times were preferable to the usual 10-minute appointments as they were able to discuss wider issues with their nurse.

'It was a polite conversation…asking how things are going in your life…not medical straight off…' (PTP001, control group)

'It wasn't pressurised or pushed, you know what I mean… you couldn't do it in ten minutes…' (PTP002, control group)

A total of 4 (2 intervention, 2 control) patients interviewed felt motivated by the frequency of the appointments.

'I saw it as accountability with the stuff that was put in place for me, that kind of discipline worked and helped…' (PTP015, intervention group)

'It actually felt like I wasn't alone with the diabetes, like someone really cared… it was much easier for example to check the blood sugar levels because I knew in one week time…someone will ask me about it.' (PTP004, control group).

Three patients (control group) commented that they miss the extra appointments and support now that the study has finished.

'I was a bit wary to be quite honest and I think rightly so because you had that support for that year, and then to suddenly go to nothing.' (PTP002, control group)

However, 4 patients (2 intervention, 2 control) felt that the appointments were too frequent.

'It's awkward and you feel as if… you're over here every day of the week.' (PTP017, control group).

Three patients in the intervention group were also dissatisfied with the content of their appointments.

'I felt it should be more informative, and if I didn't ask, nothing would have been said…it should be more regulated.' (PTP009, intervention group)

'I don't think she elaborated on her training really.' (PTP011, intervention group).

2: Barriers and Facilitators to Behaviour Change

A total of 10 patients (6 intervention, 4 control) felt they made positive changes to their diabetes management as a result of participating in the D6 Study.

Six intervention group patients reported positive behaviour changes as a result of their sessions with the D6 nurse.

'Very informative…opened my eyes to a lot of things…my way of eating, my way of living…what she was getting me to do, to say to myself, you can deny it if you want but it's here and you need to address it…' (PTP018, intervention group).

'She was very, very helpful to me because it helped me a lot by writing and knowing what I'm eating and I'm doing wrong things in my body with the sugar.' (PTP003, intervention group)

'I started to introduce a lot of wholemeal bread and all that, and that helped a lot.' (PTP011, intervention group)

'The first change, the dramatic change is the insulin, so I'm happy about that.' (PTP012, intervention group)

However, patients also experienced barriers to behaviour change, including having other priorities over managing their diabetes, mentioned by 7 patients (4 intervention, 3 control).

'I just get my priorities wrong… this is the most important thing but something else comes up and I can't make the meeting and it goes out of the window.' (PTP018, intervention group).

'*Depression just sometimes overrides the diabetes.' (PTP002, control group).*

Five patients in the intervention group denied that their diabetes was a problem.

'I'm all right, my diabetes, no problem, no problem.' (PTP005, intervention group).

Three patients (2 intervention, 1 control) described how a lack of symptoms meant they weren't motivated to manage their diabetes effectively.

'Well for me, I don't feel that sick, so the longer appointment she give me, it doesn't make any difference' (PTP007, intervention group)

Four patients (2 intervention, 2 control) felt that they were addicted to food or sugar.

'The thing is food is a drug, it's literally a drug and it's very hard to avoid something you really like eating.' (PTP 004, control group)

'Well I've been told not to eat sugar, but I'm afraid I'm addicted to it.' (PTP001, control group)

3: Positive and Negative Aspects of Nurse Manner

Patients made positive and negative comments about aspects of nurses' manner or behaviour.

Ten patients (7 intervention, 3 control) made positive statements about the manner of their D6 nurse.

'She's lovely… if she's strict with you then you took notice!' (PTP017, control group)

'She was very good… very clear… she was always very personable as well.' (PTP015, intervention group)

'It was someone that was concerned about the patient and which makes a hell of a difference to someone that just goes in and oh, you don't know what you're talking about, get out sort of thing.' (PTP001, control group)

However, 3 patients (1 intervention, 2 control) felt a lack of empathy from their nurse.

'When I first met her I thought she was a little bit of, not to say aggressive, but…' (PTP016, control group)

'She has gradually got angrier and angrier with me.' (PTP019, intervention group)

4: Reasons for Taking Part

Eight participants discussed their reasons for taking part in D6 (5 intervention, 3 control), with some patients feeling they were taking part to help others, or to fill the time.

'I don't mind that, since I have retired I've got all the time.' (PTP012, intervention group)

'Yeah I don't mind if it's helping someone.' (PTP016, control group)
'No it was to help other people, I thought well if they can learn something from me, you know.' (PTP017, control group)

Others didn't understand why they were taking part.

'This was for a survey for whatever it was, what we was doing wasn't it?' (PTP020, intervention group)

'I didn't really understand what I was doing but I just took part in it.' (PTP019, intervention group)

'…It's a wee bit of company and a good chinwag…' (PTP02, control group)

Summary of Key Findings

Patients felt they benefited from spending extra time with the nurse, yet there was no significant improvement in HbA1c.

Patients reported barriers to their participation in D6, including having priorities other than managing their diabetes, denying that their diabetes was a problem, and feeling addicted to food or sugar.

Patients reported feeling positive about their participation, yet were unclear why they had been asked to take part in the study.

Discussion

The aim of this study was to explore patients' experiences of taking part in a psychological intervention, D6. The most important findings identified from emergent themes included perceived positive impact of spending extra time with the nurse on patients' diabetes self-management and barriers to their attendance at D6 appointments. Patients in both control and intervention groups reported making positive changes as a result of additional, extended appointments, and patients in both control and intervention groups described feeling motivated by the extra sessions, yet no significant change was observed in HbA1c. Patients also reported a range of barriers to attendance despite 72% of the sample being retired or unemployed. These barriers included having other priorities and denying that diabetes is a problem.

A strength of this study is that it was developed a priori as part of the process evaluation of D6 and the data were collected without any knowledge of the main study outcome. The sample was also representative in terms of gender and age.

A limitation is that the main study data had been analysed before the interview data analysis had been concluded and it is therefore not possible to rule out any potential bias in interpretation. It is also not possible to generalise the results to the wider D6 sample, although the findings may be transferable. Transferability in qualitative research refers to the ability of future researchers to assess shared characteristics between their own population under study and that of previous research. Providing rich and 'thick description' is essential to enable future researchers to engage in transfer of results (Guba & Lincoln, 1985).

The sample drawn for this qualitative study was not ethnically diverse, despite a representative D6 sample. It may be that non-white patients failed to engage with the study as a whole as it failed to deliver the D6 therapy in a culturally sensitive way. Marin defined culturally appropriate interventions as those which are based on the cultural values of the group of interest and that therapeutic strategies are based on the

expectations and behavioural preferences of the ethnic groups under study (Marín, 1990). It is possible that D6 did not meet these criteria.

There was a high rate of non-response to invitation to participate in this qualitative study. In order to qualify for inclusion in D6, patients were required to have had persistent sub-optimal glycaemic control over an 18-month period, defined initially as HbA1c ≥ 69.5 mmol/mol (equivalent to 8.5%) on two occasions. This was then lowered to HbA1c ≥ 64 mmol/mol (equivalent to 8%) due to delayed recruitment but still represented significant poor control. It may be that this group of patients represents a particular challenge to healthcare services in that they are resistant to change via this relatively low key psychological approach. These patients have had diabetes for a long time and it may be that various attempts to support their change over the years by methods such as structured education, nurse and dietary counselling have failed. We know that their GP is aware of their persistent sub-optimal HbA1c due to pre-existing QOF data, so there is another explanation for their lack of control. The number of sessions attended by the D6 patients who participated in this qualitative study shows that they were not representative of the D6 sample in this respect. We therefore cannot conclude that the *Barriers and Facilitators* to participation they reported are representative of those who failed to attend a larger number of sessions. Recruitment stopped at 18 patients as saturation of themes had been reached, but considering this bias in the sample, it would have been beneficial to extend recruitment in an attempt to capture the views of patients who had attended fewer sessions. However, this would have necessitated a recruitment period longer than was practical for this PhD. Ideally, interviews for this qualitative study would have been conducted close to the date of patients' last D6 session, but a third were conducted 6-8 weeks later. It is possible that patients did not recall some details that may have been of interest.

The barriers to behaviour change identified included not prioritising diabetes management, denying that diabetes is a problem and feeling addicted to food or sugar. The finding that patients are not prioritising diabetes management in particular is consistent with findings from a qualitative exploration of D6 nurses' views on taking part in D6 (Graves et al., 2016), where nurses described their own perceptions that patients were reluctant to make changes to their diabetes management and failing to

engage (described in Chapter 7). This is consistent with the wider qualitative literature on diabetes management. For example O Connor et al conducted focus groups and in depth interviews with 34 diabetes patients in New England who had previously participated in a 4 day diabetes education programme. They found that patients who failed to show less than 20% improvement in HbA1c at follow up were more likely to view diabetes as not serious, were more fearful of insulin, did not make adequate changes to their diet and were less accepting of their diagnosis (O'Connor, Crabtree, & Yanoshik, 1997). Cohen et al conducted 'guided ethnographic interviews' with 39 people with T1D and T2D and 15 healthcare providers and found that more than half the patients felt their diabetes was not severe and only a minority of people developed complications. The authors concluded that accepting the seriousness of diabetes was necessary before management could be prioritised and speculated that this could take several decades post diagnosis (Cohen et al., 1994).

A possible explanation for D6 patients not prioritising their diabetes management may be that the sample was drawn from a population with persistent sub-optimal glycaemic control and an average disease duration of 10 years who were likely to exhibit lower levels of commitment to self-management. This is consistent with other studies, which have found that a major barrier to the management of T2D is patients' unwillingness to change their habits, and this represents a more significant barrier to change than their lack of knowledge of the risks involved (Jallinoja et al., 2007; Jansink, Braspenning, van der Weijden, Elwyn, & Grol, 2010). Knowledge alone appears to be insufficient to bring about behaviour change. It may also be that nurses were not confident in discussing in-depth diabetes management at the frequency and length required by D6 appointments, due to their varying experience and knowledge of T2D. The findings may also represent a lack of willingness by the nurse to become involved in patients' mental health management, consistent with findings in CHD management, where nurses did not feel competent to engage patients about mental health issues. A qualitative interview study exploring practice nurses' experiences of managing depression in a sample of CHD patients in primary care found that 11 nurses expressed uncertainty as to their perceived role and responsibility in managing patients' mental health issues. They also reported a lack of training, interest or time (Barley, Walters, Tylee, & Murray, 2012). Qualitative studies exploring aspects of diabetes care show however that patients expect more from their healthcare provider

than checkups and prescriptions. For example, Wikblad et al conducted a qualitative study with 55 T1D patients in Uppsala, Sweden. They found that patients wanted 'more than laboratory measurements' and that they wanted a more holistic approach to their care. They also found that patients with the most satisfactory metabolic control had the best experiences with healthcare providers, and that those with 'unsatisfactory control' had to conceal their true behaviours (Wikblad, 1991). It may be that D6 nurses did not have the skills to elicit information from patients that they felt uncomfortable providing.

The current study also revealed that patients were not always clear about their reasons for participating in D6, stating that they decided to participate due to a desire to help other patients, rather than to improve their own diabetes control. Some patients didn't appear clear on the purpose of the study, and there was a general sense that patients took part because they were asked to by their healthcare provider. This is consistent with research into patient participation, which has found that some patients are more passive than others due to a complex interplay of personal, physician and contextual factors or that their participation is altruistic rather than a motivation to achieve better health for themselves (Street & Haidet, 2011). This group of patients is also likely more difficult to engage as the intervention was targeting a 'hard-to-reach' population (defined in this context as patients who rarely engage with their healthcare provider) with persistent sub-optimal control. It may be that these patients have a history of attending appointments yet not engaging with their content in a meaningful way.

A further limitation of the study is that the researcher conducting the interviews was also a researcher on the D6 Study, responsible for recruiting patients and, in some cases, performing administrative tasks relating to their participation, such as calling to remind them of appointments. While only 3 patients who participated in this qualitative study were recruited into D6 by the researcher, it is possible (although not certain) that she had contact with all of them via telephone.

The problem of researcher bias in this qualitative study was not adequately addressed via the practice of reflexivity. Reflexivity involves reflecting on the way research was carried out and understanding how that process can affect outcome (Hardy, Phillips, & Clegg, 2001). Reasons why a researcher may be biased include i) psychological

discomfort (ii) lack of preparation to conduct the interviews and iii) the researcher not conducting interviews in an appropriate manner (Mehra, 2002). In the current study, it is the degree of affinity the researcher had with participants that should have received closer scrutiny. Data may have been missed due to the tendency of researchers to 'only discover what they think they don't know, rather than opening up their inquiries to encompass also what they don't know they don't know.' (Chenail, 2011). The interview schedule was piloted with 2 participants, with 2 interviews coded by an independent rater in an attempt to triangulate data. However, a reflexive diary would have represented a further appropriate measure.

There is an argument that all researchers should use a reflective diary, regardless of epistemological position (Nadin & Cassell, 2006) although it is particularly important for the qualitative researcher. A reflexive stance when conducting research allows the researcher to adopt a position of critical self-exploration. A reflexive diary may take the form of a notebook or computer document. With the progress of this thesis in mind, a reflexive diary may have been beneficial throughout the D6 timeline, in order to record thoughts and frustrations during previous interactions with patients, which may later have affected collection of data for this qualitative study. It would also have been appropriate to make notes on the development of interview schedules, discussions with supervisors and other colleagues, and to track the process of data collection throughout (Nadin & Cassell, 2006). Reflections on interviews with patients could have included thoughts on how well the interview was conducted as a social encounter, any emergent themes, the researcher's feelings throughout the interview (which may have influenced time spent with the participant, and the extent of follow up questions asked) and methodological considerations such as efficacy of the interview schedule.

'Interviewing the investigator' is an additional technique which may be employed in order to reduce potential bias. In this approach, the researcher assumes the role of study participant while a supervisor interviews them, or the researcher can assume both roles. An attempt to recreate a setting similar to that in which actual interviews will be conducted should be made wherever possible and the interview recorded. The interview recording should be reviewed and critiqued by supervisor and researcher and notes made on what worked well and what did not. Questions for prompting and

probing can be judged on their success or not in extracting information and any reactions to what is said (or not said) analysed. Modifications can be made to the interview schedule. (Chenail, 2011) Responses, frustrations, thoughts and impressions may be recorded in a reflexive diary.

The researcher was also responsible for generating the interview schedules for the qualitative study, and in doing so became 'an instrument through which data for the study [were] collected or generated' (Chenail, 2011). The researcher themselves becomes a tool throughout the research process, and it is their interaction with participants which facilitates the flow of communication and generates data. The use of open-ended questions is designed to ensure that respondents are free to answer in their own words as far as possible. Follow up questions for prompting and probing are then employed. However, it can take many years to master the skill of qualitative interviewing, and it is possible that some data were missed (Sofaer, 2002).

Finally, it is not possible to generalise the results of this qualitative study to the D6 population as a whole due to the high rate of attendance among the sample at D6 appointments, when the majority of D6 patients did not attend the full 12 sessions according to protocol. They do however represent a small sample of poorly controlled T2D patients who, despite attending appointments and expressing enthusiasm for behaviour change, do not make sufficient lifestyle changes to show clinical improvement.

Conclusion

This study found that while patients may report benefits from participating in a study such as D6, these do not translate to actual changes in behaviour and glycaemic control. While patients made positive statements about therapy, a significant minority disagreed. This suggests that more work is needed to establish whether practice nurses need additional training or whether the idea that they can be trained to deliver psychological skills in primary care should be abandoned.

Chapter 9: Discussion

Overview

This thesis has made the case for the importance of process evaluation, reviewing the evolution of the field and its potential to interpret psychological interventions. A preliminary framework was proposed which included qualitative and quantitative methods, and the feasibility of this framework to deliver a process evaluation was tested on a cluster RCT of a psychological intervention to improve glycaemic control in T2D.

Aims of this Thesis

The specific aims of this thesis were i) to review existing frameworks and methods for conducting process evaluations (Chapter 3); ii) to apply the findings of this review to develop a theoretical framework for process evaluations of psychological interventions (Chapter 3 and 4); iii) to test the face validity of the framework on a nurse-led psychological intervention, the D6 cluster RCT, to improve glycaemic control in T2D (Chapters 5-8).

This final chapter will summarise key findings from the literature reviews and the application of the theoretical framework to D6. The feasibility of the framework is assessed and a revised version proposed. Strengths and weaknesses of the methodological approaches taken in this thesis are discussed, and opportunities and challenges for future research are considered.

Summary of Findings

The scoping of the literature on theoretical underpinnings of PE (Chapter 3) led to an overview of the history and evolution of process evaluation theory and methodologies. Process evaluation has had a rich but chequered history beginning in the 1960's when the concept was introduced but not formally described, with many

researchers attempting to measure components in the absence of a framework. The original concepts of process evaluation were founded in health education in the late 1990s, and several theoretical frameworks produced over the following 3 decades. Baranowski and Stables (Baranowski & Stables, 2000) defined an 11 component framework based on a large scale public health intervention which was not widely adopted but laid the foundation for future researchers such as Linnan and Steckler (Linnan, 2002), who proposed a tighter, 7 component framework. This framework enjoyed some success but was criticised for its lack of attention to intervention context. Saunders et al (Saunders et al., 2005) built on the framework but failed to test it in real world conditions and the model was not widely used. A further framework by Grant et al focused on suitable methodologies but was firmly grounded in the RCT design with a heavy focus on quantitative measurement and minimal qualitative methods (Grant et al., 2013). In recent years the MRC produced guidance that has been more widely used but criticised for its lack of adaptability to specific research designs, lack of guidance on methods and failure to tackle the synthesis of quantitative and qualitative methodologies.

While each framework had merit, no single example was sufficient for application to complex interventions such as modern psychological interventions. The scoping study allowed for identification of recurrent concepts, for example, Baranowski and Stables' components of 'initial use' and 'continued use' overlap with 'reach' while the concept of 'exposure' overlaps with others' definitions of 'dose received'. Components were amalgamated into a new preliminary framework, which offered a checklist approach for application to complex interventions. An attempt was made to synthesise components into a single framework for the purpose of conducting process evaluations of psychological interventions. The 12 components proposed were *Formative Process Evaluation; Acceptability and Social Validity; Recruitment; Dose Delivered; Dose Received; Programme Implementation/Fidelity; Contamination; Provider Experience; Participant Experience; Context; Barriers and Facilitators; and Adoption* as summarised in Figure 3.4.

The feasibility of the framework was tested on a systematic review of psychological interventions to improve glycaemic control and other biomedical outcomes in T2D. It was used to identify and describe process evaluation components studied and methods

used. T2D was deliberately chosen for pragmatic reasons as well as being a common clinical condition. The review found that most RCTs had conducted very minimal process evaluations. The most commonly studied components of process evaluation were *Dose Delivered*, *Fidelity* and *Participant Experience*. The most understudied components were *Formative Evaluation*, *Dose Delivered, Provider Experience* and *Barriers and Facilitators*. The most commonly used methodology was quantitative session attendance data measuring *Dose Delivered,* for example patient attendance at therapy sessions. The next most commonly used process evaluation methodologies were ratings of audiotaped intervention sessions assessing *Fidelity*, structured questionnaires assessing treatment satisfaction (*Participant Experience*) and open-ended questionnaires assessing *Participant Experience*. Observational methods and semi-structured interview were the least employed methodologies.

The scoping study and literature review highlighted the need and provided very preliminary face validity for, a user friendly, consensus framework for delivering process evaluations of psychological interventions. The proposed framework was tested further on an RCT of the effectiveness of a psychological intervention to improve glycaemic control in T2D, the D6 study.

Summary of the Process Evaluation of D6

Findings are summarised according to process evaluation component.

Formative Process Evaluation

Formative Process Evaluation ensures a programme is feasible, appropriate and acceptable (Saunders et al., 2005). Conducting formative theoretical and practical evaluation prior to the development of an RCT is likely omitted from process evaluations due to time and budgetary restrictions. Formative evaluation may also be considered a standard component of a research programme and therefore not recognised as a process evaluation component. Development of an RCT may include PPI; collaborative presentation and discussion; consultation with allied healthcare

professionals; consolidation of results from previously conducted RCTs and observation from researchers' professional practice.

A feasibility evaluation of D6 occurred prior to the lifetime of this thesis, and was not formally described as *Formative Process Evaluation*. The senior investigators applied their learning from a very closely related study, the ADaPT Study (Ismail et al., 2010). This 3 arm parallel RCT compared whether (i) MI + CBT compared with usual care (ii) MI compared with usual care or (iii) MI + CBT compared with MI was more effective in improving glycaemic control in people with type 1 diabetes when delivered by hospital based nurses with additional training in these techniques. They conducted a fidelity assessment alongside the RCT, analysing therapeutic sessions for themes. Their findings that an integrated MI and CBT approach could be taught to diabetes nurses who could reach basic competency and this could lead to small but clinically significant improvements in glycaemic control was considered sufficient on a theoretical basis. They made the assumption that 'nurses are nurses' and their specialism or the conditions they work with are not relevant and therefore it was acceptable to transfer the training from a hospital based diabetes nurse to a primary care practice nurse (D6). The former specialises in in-depth diabetes and often of a higher agenda-for-change grade whereas the latter has a broader range of skills perhaps at less depth. If a formal *Formative Process Evaluation* or feasibility study of D6 had been conducted this assumption may have been challenged and may have led to a different training programme.

Formative Process Evaluation also encompasses the process of mapping theoretical underpinnings onto intervention components. In D6, the 6 psychological skills taught were drawn from MI and CBT. However, the mechanisms by which MI asserts its effects remain poorly understood (Romano & Peters, 2016). The components of client-centeredness and facilitation of change talk are of utmost importance in Miller and Rollnick's theory of MI and may offer the best explanation of how MI may produce behaviour change (Romano & Peters, 2016). Miller and Rose offer two causal hypotheses focusing on these components, which they classify as 'relational and technical' and which aim to account for the effect of MI (Miller & Rose, 2009). The relational hypothesis is concerned with the combination of Empathy and MI Spirit and how together they may evoke behaviour change. The technical hypothesis

posits that the therapist's consistent and proficient use of MI-adherent behaviour will elicit and reinforce change talk and that this change talk is related to behavioural outcome. The components of MI Spirit, Empathy and Adherence to MI were identified as central to the D6 intervention and measured as part of the *Fidelity* study described in Chapter 6 and discussed later in this chapter.

Acceptability and Social Validity

It was not possible to apply the *Acceptability and Social Validity* components of the proposed framework as the D6 study had started prior to the lifetime of this thesis. The acceptability and social validity of a proposed RCT is concerned with whether or not an intervention is feasible and acceptable to potential participants and involves pilot or exploratory studies that aim to assess full-trial feasibility for example using PPI groups. While these represent important process evaluation components, it may be that they can be more usefully collapsed into *Formative Process Evaluation* in order to simplify the framework. A revised process evaluation framework is presented later in this chapter.

Recruitment

Recruitment processes are reported as part of CONSORT guidelines and commonly discussed as a limitation or strength in the main RCT paper. They are also a crucial aspect of a process evaluation but are not often described as such. General practice cluster uptake to D6 was low (20%), despite the offer of generous nurse backfill payments (£10,000 per practice). A possible explanation for this is a cohort effect of lack of resources within general practices in combination with national restructuring of primary care services. Practices may also prioritise meeting QOF targets due to financial incentives, or there may be staff shortages, for example of GPs. Anecdotally many practices said that they were in debt but did not want the backfill because they did not have a nurse or did not want to release the nurse. It is possible that uptake of D6 would have been greater in a suburban setting outside London, but the population would not be representative of the ethnic and social diversity of people with T2D as was the case with D6.

Recruitment processes are considered and potentially amended throughout the RCT. As discussed in Chapter 5, patient recruitment strategies for D6 were amended to address difficulties recruiting from a poorly controlled T2D population. Original inclusion criteria required one HBA1c result ≥ 64 mmol/mol% (equivalent to 8%) in the past 18 months but this was amended via research ethics committee to 2 HBA1c results ≥ 64 mmol/mol%, once in the past 18 months and once at recruitment, in order to better capture a persistently poorly controlled population. HbA1c was also lowered from 69.5mmol/mol% (equivalent to 8.5%) to 64 mol/mol (equivalent to 8%).

The D6 study was also slightly underpowered at 77% (versus target of 80%) and it may be that face-to-face recruitment strategies may have been more effective, if labour intensive. However, this was a pragmatic design implemented in a real world setting (Eakin et al., 2014).

Dose Delivered

Patient attendance was a problem in D6, with average 50% attendance rate. Half the patients therefore did not receive the full dose of the intervention. Explanations for this could include that patients may have wanted more help to control their T2D but did not want to make the practical steps towards attending sessions. They may also have agreed to participate in order to please the D6 researcher or practice nurse without any intention to take part, or may not have fully comprehended the commitment to the study even though they had given informed consent, or changed their minds. Patients may also have experienced barriers to attendance, discussed further below.

Dose Received

The extent of the *Dose Received* by participants is reported less frequently than *Dose Delivered* in RCTs of psychological interventions. The terms are hard to separate and may be more useful in combination. This is a well-known problem in the field of pharmacological prescribing. Many patients do not adhere to their medications as

prescribed (Osterberg & Blaschke, 2005) and there has been extensive research into the difference between prescriptions issued and those collected (Hess, Raebel, Conner, & Malone, 2006), or prescriptions issued versus medications self-administered (DiMatteo, 2004). Adherence to a dose of medication is notoriously hard to measure and even administration of medication can be partial or intermittent (DiMatteo, 2004). However, while getting a prescription (*Dose Delivered*) is an action separated from ingesting a tablet (*Dose Received*). It may be useful to combine the concepts of *Dose Delivered* and *Dose Received* in future process evaluations of psychological interventions where both are taking place simultaneously (e.g. during a therapy session). It may therefore be useful to combine the two terms so that *Dose Delivered* + *Dose Received* = *Adherence*. If the minimum acceptable level of an intervention was delivered to a participant and it is accepted that they also received each dose then it is reasonable to conclude that the minimum amount of intervention required has been delivered as intended. The concepts of *Dose Delivered* and *Dose Received* have been combined as *Adherence* in the revised framework presented later in the chapter.

The mean number of D6 doses received was lower than intended. There was no evidence of an association between the number of D6 intervention doses delivered and HbA1c at 12 month follow up. A meta-analytic review of self-management education interventions for adults with T2D found that dose was significantly associated with greater effect sizes for diabetes knowledge and metabolic control. However, this effect did not extend to self-management behaviours (Fan & Sidani, 2009). Assessing the dose-response relationship in psychotherapy is even more complex with evidence that acute and chronic symptoms may improve at different rates, in different long-term conditions and settings (Hansen, Lambert, & Forman, 2002). It may be that different strategies or intervention types are necessary to address different aspects of self-management.

Programme Implementation/Fidelity

Fidelity is a commonly studied component of process evaluation. An explanation may be that *Fidelity* is an established concept within the literature. *Fidelity* enables the researcher to establish whether a successful intervention worked as a result of the

intervention itself, or another factor that was added to the intervention or omitted from it. Conversely, if an intervention did not work, we cannot be sure that non-significant results were due to the failure of the intervention itself or a failure of implementation.

Overall, the *Fidelity* analysis showed that D6 was not implemented according to protocol, and provided information about the absence of specific competencies. This data is crucial for accurately interpreting the results of a trial, which aimed to assess whether or not practice nurses can be trained to deliver psychological skills in place of mental health professionals. It may be that they cannot, and that the delivery of MI is best suited to specialists in psychological healthcare. If nurses or other allied health professionals are to be trained in psychological skills, it may be that the best approach is to select nurses based on their previous experience and aptitude for reaching required competencies. Allowances were made for the fact that D6 skills were delivered as part of research consultations and as such did not represent real world practice.

Contamination

Most complex psychological interventions cannot be delivered blind to participants or providers and it is therefore difficult to contain delivery of treatment within the intervention arm. It may be that researchers consider strategies such as cluster randomisation sufficient to control for potential contamination. However, it is possible that participants may still receive the intervention from other sources. This was observed within D6, as a nurse in the control group attempted to learn D6 skills and deliver them to her patients. This was accounted for in the main RCT analysis.

It may be helpful to combine the component of *Contamination* with that of *Programme Implementation/Fidelity* since the two concepts are closely related. Fidelity may encompass the verification of the occurrence of essential components, in addition to the absence of treatment contamination (Leeuw, Goossens, De Vet, & Vlaeyen, 2009). This is reflected in the revised framework.

Provider Experience

The process evaluation of D6 showed that nurses perceived the D6 intervention as useful but that it required significant role readjustment on their part. When combined with the results from the fidelity analysis, which showed that the majority of nurses did not deliver the intervention as intended, this provides some explanation for the non-significant D6 findings.

Further barriers to implementation of the D6 protocol were revealed by a qualitative interview study exploring nurses' experience of taking part. Nurses cited many patient behaviours as barriers to their practice, including lack of attendance at appointments, lack of willingness to commit to scheduled appointments and patients not prioritising diabetes self-management, something which may be explained by the fact that the D6 sample was drawn from a hard to reach population with 10 years average disease duration. Patients were chosen because they had persistent sub-optimal glycaemic control and consequently were likely to have had low levels of commitment to self-management and poor records of attendance at healthcare appointments.

In addition, nurses cited many barriers to practice, including some resentment towards the lack of financial compensation for their time commitment (despite financial compensation being made to their practice) and the requirement that they assimilate D6 practice into their already busy workload. Nurses also struggled to deliver specific aspects of MI therapy such as complex reflections, which suggest that these skills may be particularly difficult for a non-specialist to provide.

Nurses were concerned about over-stepping professional boundaries, particularly when dealing with highly emotive consultations, and many felt they were not properly qualified to deliver the D6 intervention. If allied health professionals are to be trained to deliver psychological skills as part of routine care then it is essential that this barrier is addressed in future research. Since it was also found that nurses perceived D6 skills as valuable and transferable in a clinical setting, it may be the problem is one of confidence in using the skills, and not one of motivation to learn them.

The organisational context also appeared to be crucial in determining whether D6 nurses were able to implement the intervention according to protocol, with some nurses revealing that they felt under supported by their practice. They highlighted the need for future research to provide support from other departments within the general practice, such as IT and reception teams, in order for an intervention such as D6 to be successfully implemented.

Participant Experience

The literature review showed that *Participant Experience* was a commonly measured component of process evaluation. Although qualitative interview studies are time consuming to conduct, transcribe and analyse, rich data are captured and the population is easily accessible thanks to their established participation in the main RCT.

There is significant conceptual overlap with *Barriers and Facilitators* and *Fidelity* in that the data captured by participant experience helps to explain the no-dose effect of D6. However, since qualitative interviews exploring *Participant Experience* are capable of capturing data on every aspect of participation in the study there is an argument for its continuation as a separate component of process evaluation.

The process evaluation of D6 showed that participants felt they benefited from spending extra time with the nurse, yet the D6 RCT analysis showed no significant improvement in HbA1c. Their perceived benefits did not translate to actual behaviour change. Any benefits that patients did derive from the intervention may have arisen as a result of a power dynamic between the patient and provider, the former relying on the latter to provide crucial healthcare. A social desirability effect may have provided an incentive to change behaviour. Patients reported positive aspects of consultations including frequency, increased diabetes knowledge and positive nurse manner. A mechanism of action of the D6 intervention may have been a sense of collaboration between patient and provider. Anecdotal data from tape recordings also suggest that nurses' tone of voice was often harsh and critical (bearing in mind that raters did not know patients' study arm allocation), and it may be that intervention nurses who had received training in MI demonstrated preferable consultation styles.

Patients in the control group may also have reported benefits from spending extra time with the nurse as a result of the 'treatment as usual' control condition study design of D6. This type of control group assumes that patients ordinarily receive a certain level of care from nurses, but this may not be the case. Nurses may have been working harder to provide 'usual care' as recommended by NICE and adapted for the local population (NIHR, 2002) as a result of participating in the study (Freedland, Mohr, Davidson, & Schwartz, 2011). In addition, the D6 research assistants made frequent visits to each nurse to ensure they were supported administratively and also helped them contact D6 patients for appointments, which may have resulted in patients attending 'usual care' appointments more frequently. It's possible that the D6 usual care control condition systematically improved the 'usual care' received by control participants. However, while 'no treatment' control conditions are suitable for an effectiveness trial of a drug at a university teaching hospital for example, it would not have been ethical to use a 'true' control condition in an efficacy trial such as D6 due to the risks of depriving participants of their routine monitoring and therapies (Freedland et al., 2011).

Context

The literature review revealed that *Context* is rarely studied as part of a process evaluation. It concerns the extent to which the wider context within which the intervention was implemented has the potential to effect outcome.

An evaluation of *Context* was planned as part of this PhD, and presented to the NIHR as part of a PhD Research Fellowship application (2012). The proposed thesis was shortlisted and the candidate invited to interview. However, the panel felt the thesis was too ambitious in its scale and it was not funded. The component of *Context* was therefore excluded as a much larger piece of work, on the advice of the panel.

Exploration of the *Context* component of process evaluation may represent a costly endeavor, as examining contextual variables such as workplace systems and team communication channels may require methods which are labour intensive and

resource-consuming. Proposed methodologies for assessing *Context* included 2 separate studies; first, an ethnographic examination to observe organisational processes and changes in GP practice working as a result of D6. Proposed methods included shadowing a purposive sample of D6 nurses with the aim of observing the impact of D6 on working patterns and other organisational changes, using prompts to elicit process data from D6 nurses and colleagues/other staff. This data could be analysed for themes and mapped within and across GP practices. Analysis could be conducted using NVivo software where appropriate.

The second proposed study was an examination of national and local policies on training health professionals in psychological skills to support patients' self-management. The aim would be to map current understanding, expectation and delivery of education and training needs in psychological skills for health professionals (especially nurses) delivering diabetes care at local (Clinical Commissioning Group), regional and national level. Proposed methods included a scoping study of policy documents and grey literature and interviews of key leaders in statutory and third sector organisations responsible for policy (NHS Diabetes, NICE, Diabetes UK, GP leads for diabetes in Commissioning Groups within D6). Data could be analysed to produce a thematic framework against which the implementation of policies on training health professionals to delivery psychological therapies would be examined.

Although these studies were not funded, there were a number of observations made, which may explain contextual factors. For example, difficulties recruiting general practices into D6 were potentially confounded by the coincidental restructuring of primary care services, with the responsibility of management for T2D patients shifting from secondary to primary care, putting additional strain on services. It may also be that there is currently no societal desire for psychological support for T2D as there is for T1D. For example the ‘cognitive and psychological effects of living with type 1 diabetes’ are in the top 10 research priorities for Diabetes UK (UK, 2011) but T2D is not. It is possible that the D6 intervention was not tested at the right time. Further contextual factors that may have contributed towards the null finding could be that the inner city setting within which D6 was implemented represented an

inappropriate setting for a psychological intervention when patients are already struggling to cope with the demands of chaotic city living.

Barrier and Facilitators

Barriers and Facilitators to intervention implementation were also not commonly reported, potentially due to financial and time related restrictions. Exploring the reasons why patients and healthcare providers felt they were not able to engage with or deliver the intervention as planned, or vice versa, represents another drain on what may be limited resources, particularly once the main RCT data collection has finished and focus is shifted towards analysis.

Important barriers to diabetes self-management were revealed by the qualitative participant study, which supported the findings of the qualitative study conducted with providers and vice versa. Patients reported feeling they had other priorities more important than managing their diabetes, consistent with the finding from the nurse study indicating that patients were unwilling to engage and reluctant to make changes to their diabetes self-management. It may be that interventions designed to tackle social and psychological issues together could be more effective in managing diabetes (Doherty et al., 2016).

A further finding that emerged from patient interview data was that many patients were unclear why they were participating in D6. Reasons for participation included the desire to help others, or the fact that they had been asked to do so by their healthcare provider. This again highlights the difficulty of attempting to enhance motivation to change in such a hard to reach population, who have little or no motivation to engage with their diabetes management.

Adoption

None of the process evaluations reviewed reported data on the component *Adoption*. This is unsurprising considering that data do not emerge until several years after the main RCT has ended. It also raises questions about the usefulness of the *Adoption*

concept in the process evaluation framework. It has therefore been removed from the revised version.

Overall Assessment of This Process Evaluation Framework

The application of the framework to D6 yielded three useful sets of data in addition to that collected as part of the D6 RCT including i) fidelity data, which revealed that the intervention was not implemented as planned ii) qualitative data on barriers to implementation experienced by nurses, which have implications for the design of future research and iii) qualitative data from patients that were consistent with the barriers cited by nurses and with what is already known about attempting to reach this particular sub-set of patients with persistent sub-optimal control.

These data will be crucial in informing the design of future research. In the absence of a process evaluation of D6, there would be no data on whether or not the intervention did or did not work as a result of the design itself or a feature of implementation. The process evaluation has told us that failure of implementation may be one part of the explanation of the outcome of the D6 trial. We also know that there were barriers to successful implementation other than nurses' competencies, which were cited by both nurses and patients and should be addressed in future research designs. The process evaluation data revealed that practice nurses may not be suited to psychological skills acquisition and that this specific sub-group of patients may not be an appropriate target for MI intervention.

The 12-component framework tested on D6 was a useful starting point for conducting a process evaluation of a psychological intervention. However, it became clear throughout testing that some components may be more usefully combined in order to avoid conceptual overlap.

Revised Process Evaluation Framework Components

Table 8.5 shows a summary of the revised 8-component process evaluation framework.

Table 8.5 A Revised Framework for Process Evaluations of Psychological Interventions

Process Evaluation Component	Description
Formative Process Evaluation	Mapping theoretical underpinnings of the intervention design onto potential active components. Pilot or exploratory studies are conducted to ensure that the proposed intervention is feasible, appropriate and acceptable to potential participants.
Recruitment	Determining the most appropriate recruitment strategies and considering their impact on study outcome. Monitoring and adapting recruitment strategies throughout the RCT to maximise uptake and efficiency.
Adherence	Dose delivered + dose received = adherence. If the minimum acceptable level of an intervention was delivered to a participant and it is accepted that they also received each dose then it is reasonable to conclude that the minimum amount of intervention required has been delivered as intended.
Programme Implementation/Fidelity	Measuring whether or not the intervention was implemented according to protocol in order to answer the question: did a successful intervention work/not work as a result of the intervention itself, or another factor that was added to the intervention or omitted from it? An assessment of contamination should be made to establish whether control group participants have received elements of the intervention.
Provider Experience	This concerns the experiences of the provider selected to deliver the intervention. There are many individual characteristics with the potential to affect outcome, including provider responses; personal beliefs and values; previous experience or training and capacity to engage.
Participant Experience	This concerns the experiences of participants who receive the intervention, their satisfaction and the degree to which they find the intervention acceptable. There are many individual characteristics with the potential to affect outcome, including participant responses; interaction between participant and interventionists; personal beliefs and values; previous experience or training and capacity to engage
Context	This refers to the environmental setting in which the intervention is implemented that have the potential to affect outcome. These may include organisational factors, systems and logistical factors, system or political factors such as local or wider national policies and economic factors such as available funding and resources.
Barriers and Facilitators	An exploration of the barriers or facilitators to the implementation of the intervention as per protocol. These may be revealed through exploration of other process evaluation components such as Provider Experience or Context.

Strengths and Limitations

There are a number of strengths and limitations of this thesis concerning the scoping study and literature review, development of the framework and its application to the D6 study.

The framework proposed in this thesis was developed as a result of the scoping study described in Chapter 3. The advantage of a scoping study is its ability to synthesise a poorly demarcated area of research, which would have been very challenging using traditional systematic review methodology. For example, a review of worksite health promotion programmes identified 307 studies alone, of which 22 published a process evaluation (Wierenga et al., 2013), and just 8 based their evaluation on a theoretical framework. A review of studies in occupational stress management which incorporated process evaluation identified 52 studies which reported on an aspect of process evaluation (Murta et al., 2007) and fewer than half presented any findings linking the process evaluation with outcome. A review of process evaluations of school based vaccinations identified 14 studies which met inclusion criteria, concluding that more controlled studies are required to provide the public health community with the best evidence and evaluation data on how best to implement school based vaccination studies (Robbins, Ward, & Skinner, 2011). These reviews show that while there are bodies of research present in a variety of fields, their results are consistent with that of process evaluation research in general, which is a poorly defined field comprised of conflicting approaches. However, despite this complexity within the literature, it is likely that studies of interest were excluded from the scoping study to the potential detriment of framework development.

Both a strength and a limitation of this thesis is that it focuses exclusively on process evaluations of psychological interventions in T2D. As the first review of process evaluations of psychological interventions designed to improve glycaemic control in T2D it represents an important step in furthering understanding of the current state of process evaluation research in this field. The literature was narrowed to a field

relevant to this thesis, exploring process evaluations of studies relevant to the T2D epidemic. The inclusion criteria for the review were generous, including studies that specified they had conducted a process evaluation, and also those which did not. This approach was chosen with the aim of identifying all attempts at process evaluation, despite terminological variation. Studies were synthesised without being limited by this considerable variation in terminology and frameworks, which in turn enabled more meaningful comparisons between studies. Establishing an a priori framework allowed for structured discussion proceeding from theoretical deduction rather than simple observation.

However, as the review could not include process evaluations of RCTs of interventions conducted in different contexts, e.g. in community settings, the findings may not be generalisable to other interventions in different long-term conditions. Much process evaluation work has taken place within the health education context, which this review does not include. It is possible that important research within the process evaluation field may have been missed due to the exclusion of this category. For example, a community based mental health promotion intervention for refugee children living in a Palestinian camp in Beirut, Lebanon highlighted the challenges and complexity of implementing a process evaluation within a severely disadvantaged community in the Eastern Mediterranean region (Nakkash et al., 2012). The Quaderoon ('We are Capable') intervention was a year-long social skill building intervention for children aged 11-14 years, their parents and teachers, aimed at promoting mental health of the children and increasing their attachment to school. The intervention was informed by stress inoculation training, improving social awareness/social problem solving and a positive youth development programme. It consisted of 45 sessions with children, 15 with parents and 6 workshops with teachers. In addition the intervention implementation and process evaluation were guided by a Community Youth Coalition group, established specifically for the project and comprising 17 Non-Governmental Associations working with youth members and residents of the camp, research team members and funders. The process evaluation focused on dose delivered, dose received, fidelity, satisfaction and reach. The process evaluation showed that session objectives were achieved and intervention activities implemented as planned although attendance was low. Children reported a high level of satisfaction with sessions. Qualitative methods such as meetings of the

implementation and research team and observational data collected by field coordinators were used to address problems with intervention delivery as they arose, resulting in changes of intervention structure and content while the intervention was in progress. Challenges to implementation included the size of the research team and corresponding variation in delivering the intervention and interacting with children. The unique context of the intervention presented significant challenges, not least the escalation of conflict between Israel and Hamas in 2008 leading to the war in Gaza. The children participating in the study were deeply distressed by political events. Other challenges to conducting process evaluation included competing demands on researchers, difficulty in conveying the importance of process evaluation to the wider research team and political events interfering with data collection. Limitations included reliance on self-report data from internal evaluators and a lack of data gathered from children participating in the intervention. This study reports a complex intervention in which process evaluation was particularly ambitious and important in revealing challenges to implementation.

A strength of this thesis is that the process evaluation strategy for D6 was developed and based on theoretical concepts. The process evaluation framework was developed as a result of literature review, summary of previous frameworks used and components of process evaluation previously studied. These theoretical constructs were then translated into research questions. The role of theory is crucial in the development of any research that may lead to evidence based practice as it enhances explanatory power and predictive capability (Green, 2000). In turn these theoretical concepts were used to develop a framework for process evaluation that is designed as a checklist for researchers. The aim was to provide an aid to planning and evaluation which can be used in a similar way to the CONSORT checklist, designed to aid researchers in the design and conduct of RCTs. One of the main aims of the CONSORT checklist is to provide completeness and transparency of reporting of results and this too, is the aim of the process evaluation checklist. The two checklists differ considerably however in the types of data they are capturing. The CONSORT checklist was designed to ensure that biases in the conduct of an RCT are minimised to reduce the risk of over or under estimating effect sizes. On the other hand, the process evaluation checklist is designed specifically to enhance the understanding of

the complexity of an intervention, by capturing all the data that a standard RCT does not.

Similar checklists designed to improve the reporting of other types of research followed the development of CONSORT, including Quality of Reporting of Meta Analysis (QUOROM) (McDonough, 2003); Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009); Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (Von Elm et al., 2008); Standards for Quality Improvement Reporting Excellence (SQUIRE) (Davidoff & Mooney, 2008); Critical Appraisal Skills Program (CASP); (UK, 2017); Template for Intervention Description and Replication (TIDIER) (Hoffmann et al., 2014)and Consolidated Criteria for Reporting Qualitative Research (COREQ) (Booth, Hannes, Harden, Noyes, & Harris, 2014).

The QUOROM statement preceded the development of PRISMA, with both designed to enhance the conduct and reporting of systematic reviews and meta-analyses. The PRISMA statement consists of a 27-item checklist and four-phase flow diagram including items considered essential for the proper conduct of systematic reviews. STROBE is concerned with epidemiological studies, SQUIRE with the reporting of quality improvement studies within healthcare settings, and COREQ with the conduct and reporting of qualitative research, specifically interviews and focus groups.

The advantage of such checklists is that they are developed collaboratively by groups of experts and as such benefit from their pooled knowledge and experience. They are also developed over many years, and are the result of large amounts of research. The original CONSORT checklist for example, was developed by 13 scientists and revised by 31 (Begg et al., 1996); PRISMA was developed collaboratively by a group of '29 review authors, methodologists, clinicians, medical editors, and consumers' (Moher et al., 2009); the STROBE website lists 20 research group members; SQUIRE was drafted by '30 stakeholders' (Davidoff & Mooney, 2008) and COREQ was developed by a research team at the School of Public Health, University of Sydney. A limitation of the proposed process evaluation framework set out in this thesis, then, is that it was developed without such a dedicated research team and the researcher's resources, in terms of expertise, experience and time available, were very limited in comparison.

Nonetheless, a clear strength of this thesis is that a process evaluation framework was developed and used, when many process evaluation studies have not.

However, a lack of standardised methods for conducting scoping studies means that selection of appropriate methodology is open to researcher interpretation and the data from a scoping study has to be interpreted without an assessment of quality as would occur in a systematic review (Davis et al., 2009). It could be argued therefore that the study presented in Chapter 3 does not delineate the methodological steps taken towards framework development clearly enough.

There are also some important limitations relating to the process evaluation of D6, in particular the study research team. The researcher responsible for conducting the process evaluation and writing this thesis was also a research assistant for the duration of D6, responsible for recruitment of patients into the trial, data collection, management of D6 nurses and trial administration. As Co-Investigator, the researcher's first supervisor was responsible for the design and overall conduct of the trial (KI). As an NIHR Post-Doctoral Fellow, the researcher's second supervisor was responsible for the setting up and overall management of the trial (KW).

The researcher's former position as D6 research assistant represents a source of bias in terms of her ability to objectively evaluate the study. Bias 'is a lack of neutrality or prejudice' (Attia, 2005) and it can occur at any stage of planning, conducting, or evaluating an intervention. While the RCT study design aimed to minimise bias using random allocation of participants and allocation concealment, the dual role of the researcher may have influenced findings. For example, the researcher supervised 9/16 nurses for the duration of their participation in D6 (helping arrange patients' appointments patients and providing administrative support), and also interviewed them for the qualitative study reported in Chapter 7. This increases the potential for social desirability bias, as nurses may have felt uncomfortable disclosing their true thoughts about D6 to the researcher, or may have wanted to gain her approval. The same problem is relevant to the qualitative study described in Chapter 8 in which the D6 researcher interviewed D6 participants (3/18 patients were recruited into D6, and later interviewed by, the researcher).

The analysis of data emerging from both qualitative studies may also have been subject to researcher confirmation bias. Confirmation bias refers to the 'seeking or interpreting of evidence in ways that are partial to existing beliefs, expectations or a hypothesis in hand' (Nickerson, 1998). It is possible that the researcher interpreted qualitative interview data with her own observations throughout the duration of the RCT in mind, although a sample of interviews from both nurse and participant qualitative studies was coded by an independent rater to address this. As discussed in Chapters 7 and 8, greater reflexivity in the conduct of the qualitative research and keeping a reflexive diary for the duration could have further addressed these potential limitations.

In addition, the positions of the researcher's supervisors as Co-Investigator and NIHR Post-Doctoral Fellow meant they were responsible for the design and overall conduct of the trial and as such may have been reluctant to identify flaws in the trial, which may have impacted on the evaluation presented in this thesis. However, the D6 study was peer reviewed before funding and monitored by an independent Trial Steering Committee and Data Monitoring and Ethics Committee for the duration of the RCT. It is therefore implicit that other senior academics considered the formative evaluation and design of the trial to be satisfactory.

While the position of the D6 researcher and her supervisors represented potential sources of bias, this thesis optimised the use of D6 by testing the efficacy of a new intervention, conducting a process evaluation and evaluating the feasibility of a process evaluation framework tested in a real world setting within a very limited budget. Other studies have shown similar results, for example, a qualitative study of healthcare professionals' perspectives of barriers and facilitators to the delivery of support for people with severe mental health problems and T2D found that healthcare professionals felt 'hard wired' to focus on their own specialism, despite acknowledging they felt unskilled in other areas, similar to the barriers cited by D6 nurses (Papachristou Nadal et al., 2020).

A strength of this thesis is that the framework was tested on an RCT of a new intervention conducted in a real world, primary care setting. Seven of 12 components presented in the original framework were studied (*Fidelity, Participant Experience,*

Provider Experience and *Barriers and Facilitators* as three stand alone studies, and *Recruitment, Dose Delivered/Dose Received* and *Contamination* as part of the quantitative primary outcome analysis). The remaining components were beyond the scope of this PhD. Data were collected and the results analysed prior to the intention to treat primary analysis of the main RCT. This removed a potential bias in the interpretation of process evaluation results. The process evaluation became even more relevant as the primary D6 outcome showed no change in glycaemic control in either the intervention or control group.

The process evaluation of D6 used both quantitative and qualitative methods to enhance understanding of the main RCT outcome data. The use of mixed methodologies is necessary to capture the range of processes and mechanisms that may explain the how and why of the effect of an intervention on the outcome. The synthesis of these two complimentary approaches mean that quantitative and qualitative data can assist in the interpretation of one another's findings, for example quantitative fidelity data revealed that D6 nurses were not competent in delivery of certain MI skills, while qualitative data revealed that they were not confident in providing psychological care to patients because they felt they were overstepping their roles as nurses. While quantitative data provides information on fidelity, dose and reach, qualitative data can provide in-depth understanding of mechanisms of action within an intervention, or reveal barriers, which have prevented its success.

However, combining data collected using quantitative and qualitative methods can be complex (Carey, 1993; Driscoll, Appiah-Yeboah, Salib, & Rupert, 2007; Fetters, Curry, & Creswell, 2013; Grafton, Lillis, Malina, Nørreklit, & Selto, 2011). The two approaches have fundamentally different philosophical underpinnings, and have given rise to different journals, funding sources, areas of expertise, sets of methods and language used (Sale et al., 2002). As a result, it may be that these methods are more appropriate as complementary perspectives within the same research design, rather than in forced combination or 'synthesis' (Sale et al., 2002). This may be particularly relevant for the study of psychological interventions where there are many levels and processes at work with the potential to contribute towards outcome.

The MRC framework for conducting process evaluations suggests that quantitative RCT outcome measures are supplemented with qualitative approaches. However, as Blackwood et al state, there is a 'fundamental ontological contradiction' at the heart of the framework (Blackwood, O'Halloran, & Porter, 2010) which concerns the difference between efficacy and effectiveness in healthcare evaluation research. The MRC framework suggests that researchers should measure both efficacy, which is 'the extent to which an intervention produces a beneficial result under ideal conditions' (Higgins & Wells, 2011) and effectiveness 'the extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do' (Singal et al., 2014), something which is impossible according to the MRC's argument that the RCT is the gold standard method for measuring trials of new healthcare interventions. There is therefore an important philosophical tension central to the MRC framework, in which the positivist assumptions of the RCT are at odds with the relativism of qualitative approaches. It is a tension between the idea that psychological research is founded firmly in data, logic and inductive inference, and the perspective that truth and knowledge exist within the human experience (Fletcher, 1996). Realistic evaluation must combine these two perspectives coherently.

Mixed methods research places quantitative and qualitative research on a continuum rather than as distinct approaches to be combined (Newman, Benz, & Ridenour, 1998). Mixed methods designs vary widely, and Tashakkori and Teddlie identified 40 types of mixed methods designs in the literature (Teddlie & Tashakkori, 2003). These approaches were summarised into 4 categories by Creswell and Clark: the triangulation design, the embedded design, the explanatory design and the exploratory design (Creswell & Clark, 2017). These designs can be further categorised as one-phase (quantitative and qualitative methods applied simultaneously) and two-phase (quantitative and qualitative methods applied sequentially) approaches. Process evaluation may combine elements of both one-phase approaches (triangulation, embedded design) and two-phase approaches (explanatory design, exploratory design). Triangulation involves combining quantitative and qualitative methods in order to play to their relative strengths and weaknesses, for example the large sample size and generalisablity of quantitative research versus the small sample size and in depth data of qualitative research. This represents the most commonly used approach to mixed methods research (Creswell, Plano Clark, & Hanson, 2003). Process

evaluations may also use an embedded design, in which one data set provides support as a secondary set of data to a study primarily designed around either quantitative or qualitative methods. An embedded experimental model may be applied as a two-phase approach, for example when the researcher has conducted a quantitative RCT but wants to collect qualitative data about participants' perspectives after the RCT has taken place, as was the case with D6. An explanatory design may be a two-phase mixed methods design in which the purpose is to obtain quantitative outcome data then compliment it with a qualitative phase, while an exploratory design may use the first dataset to further inform or develop the second (Gelo, Braakmann, & Benetka, 2008).

The use of mixed methods also opens up the possibility that they will yield divergent datasets. For example, a pilot RCT to examine the impact of welfare rights advice on 126 older people in primary care found little evidence for differences in quantitative health and welfare outcomes at 24 months after receiving welfare rights advice. However, qualitative semi-structured interview data suggested 'wide-ranging impacts' (Moffatt, White, Mackintosh, & Howel, 2006). The authors posit a lack of power in this pilot study; the ability of the outcome measures used to accurately capture relevant outcomes in an older population; and that insufficient numbers of people had received benefits for long enough to allow health outcomes to have changed when comparisons were made as explanations for the lack of quantitative difference. The qualitative study however, found that some participants experienced significant impact as a result of receiving additional financial resources, reporting a wide range of uses for the extra money. The authors devised 6 ways of interpreting the divergent data including (i) treating the methods as fundamentally different; (ii) exploring the methodological rigour of each component; (iii) exploring dataset comparability; (iv) collection of additional data and making further comparisons; (v) exploring whether the intervention under study worked as expected and (vi) exploring whether the quantitative and qualitative components match. From this detailed analysis of the discrepancies between the two datasets, the authors concluded that the divergent findings arose from the fact they were exploring different research problems; that the pilot study may have been too underpowered to detect a significant effect; and that the qualitative study may have been measuring dimensions not measured by the quantitative study, which led them to look more carefully at the

measures used and conclude they were not wholly applicable to an older population. They also sought further funding to undertake additional data collection at follow up, which verified the findings of the original study (Moffatt et al., 2006).

This study highlights the need for better synthesis and interpretation of process evaluation data. However, much of the difficulty lies in the fact that public health interventions such as D6 attempt to capture complex psychological phenomena using standardised measurement tools. While the inclusion of mixed methods attempts to address this issue, 'the practice of research is a messy and untidy business which rarely conforms to the models set down in methodology textbooks' (Brannen, 2017) and process evaluation is no different.

This thesis represents an important and original approach to conducting a process evaluation, which has been performed without the benefit of more than 100 years of study, as is the case with the RCT. The first RCT of a psychological study was conducted in the 1880's (Stigler, 1992), while process evaluation is an emerging field.

The Future of Process Evaluation

Process evaluation can be conducted in the same spirit and vigour as adhering to the CONSORT guidelines but the frameworks and methods are still in their infancy. Many researchers are time poor and will be looking for a framework that can be used quickly and easily. This will lead to cost saving measures. It is crucial that frameworks are adopted if the field is to move towards theoretical development and methodological consistency.

The MRC guidance provides the most up to date guide for researchers, but lacks a checklist (Moore G, 2014). Although representing an important advancement in the field, and acknowledging the importance of process evaluation, the guidance reads more like a review of the literature than a guidance document. In attempting to provide a 'one size fits all' approach they have produced guidelines that could be considered vague. It may be that specific process evaluation guidelines must be produced for different contexts and different long-term conditions. The framework

presented in this thesis identified the core components of process evaluation, which can be applied to evaluations of psychological interventions. The MRC is currently updating their guidance on developing and evaluating complex interventions, but running behind schedule (Moore G, 2014). Publication is expected in 2020. Perhaps the new guidance will offer more detailed instruction for researchers on how adapt the framework to their own work.

Realist RCTs

The future of process evaluation lies in the synthesis of quantitative and qualitative methods. At the heart of the MRC framework is a tension between the positivist rigour of the RCT and the relativist position of qualitative methods. Resolving this tension is key. The MRC guidance resonates with the idea of realist evaluation, which pays attention to mechanisms, context and outcomes (Pawson, 2013). In recent years there has been lively debate in the literature around the concept of 'realist RCTs' (Bonell, Fletcher, Morton, Lorenc, & Moore, 2012; Bonell, Warren, Fletcher, & Viner, 2016; Marchal et al., 2013; Van Belle et al., 2016). Realists argue that RCTs fail to account for the complexity of social causation and ask which interventions work under which circumstances and for whom (Pawson, Tilley, & Tilley, 1997), while proponents of the RCT argue that the randomisation process takes account of the complexity of social causation through study design (Bonell et al., 2012). The realist RCT aims to use the realist critique of RCTs as a method for modifying them to be more useful in the evaluation of public health interventions.

A realist RCT may be one that attempts to identify the effects of intervention components separately and in combination, in an attempt to identify the most powerful combination of active ingredients. There is a tendency in process evaluation to focus on intervention components rather than mechanisms of change. For example, a process evaluation of a pilot RCT to test the effect of microfinance and gender/HIV training on sexual behaviour and partner violence in rural South Africa determined that a community intervention component was the least effective in positively influencing outcomes. However, this conclusion was based on the poor implementation of this component rather than evidence regarding mechanisms of change (Hargreaves et al., 2010). The process evaluation also did not determine which

of the properly implemented components did or did not contribute to positive effects. Bonell et al (Bonell et al., 2016) suggest that a realist RCT with multiple arms which test various combinations of intervention components in each arm could provide a solution to this problem. They also suggest factorial trials comparing 2 intervention components and 4 groups: two groups receive individual intervention components, 1 group receives both, and 1 group receives neither (Montgomery, Peters, & Little, 2003). Realist RCTs also emphasise measurement of active ingredients, which are often already measured as secondary outcomes. For example, a school based youth programme to reduce smoking behaviour among young people measured self-efficacy as a secondary outcome and potential active ingredient influencing outcome (Winkleby et al., 2004). Ten high schools in California were randomly assigned to receive an intervention designed to reduce smoking activity, or education only. There was a significant reduction in smoking behaviour among regular smokers in the intervention versus control group, which was maintained at 6 months post-intervention. There was also a significant difference in perceived self-efficacy between intervention and control groups, which led the authors to conclude that the construct of self-efficacy may map onto an underlying casual pathway in smoking behaviour.

Realist RCTs should also attempt to formally test hypotheses relating to *Context* and its effect on outcome. A key aspect of realist evaluation is seeking to understand how an intervention works by anticipating mechanisms of action and generating hypotheses to be empirically tested (Jamal et al., 2015). Pawson and Tilley suggest using observational data to investigate how context interacts with intervention mechanisms to generate outcomes ('context-mechanism-outcome configurations') (Pawson, 2013). For example in D6, observational data on existing working patterns within GP surgeries could be used to generate hypotheses about how these patterns may affect pilot implementation of the RCT, which could be tested during the main trial. The data reported in Chapter 7 showed that D6 nurses felt they needed support from other practice staff in order to incorporate D6 into their workload. However, there are obvious potential financial and occupational barriers to testing such hypotheses.

Future Process Evaluation Purposes and Methods

There may be further purposes for process evaluation than those incorporated into the framework proposed in this thesis. Pragmatic formative evaluation could be incorporated into the *Formative Process Evaluation* component. Pragmatic formative evaluation is discussed in Chapter 3 and refers to formative evaluations of interventions that are already used in routine practice but have not yet been subjected to rigorous theoretical assessment. They are often distinguished by a lack of a robust evidence base (Evans et al., 2015). The MRC guidance on process evaluation states that if an intervention is already widely employed, then a testing phase may not be essential (Moore G, 2014). However, if there are mechanisms of change active within an intervention it is likely that they have not been sufficiently theorised or tested. For example, Evans et al conducted a formative process evaluation of a school-based emotional and social learning intervention which had been recommended as best practice in managing children's challenging behaviour by the Welsh school inspectorate. The evaluation found iatrogenic effects due to a stigmatising targeting process, which led to negative labeling of children as intervention participants, labeling of students as 'at risk' for future deviancy and escalation of deviant behaviours (Evans, Scourfield, & Murphy, 2014). Methods used to guide a pragmatic formative evaluation could reflect those used in a *Formative Process Evaluation*, including systematic review, identification of potential active ingredients, mapping of theoretical concepts and consultation with stakeholders. Pragmatic formative evaluation is an exciting area of development because it moves process evaluation beyond the assessment of the RCT. Conducting a process evaluation on an existing intervention in a real world setting means it is not only complementary to the RCT but can be applied to different types of research, for example quality improvement studies.

A process evaluation framework may also be applied as an evaluative tool in wider research contexts such as systematic review. A framework could be used to assess quality of studies included for review, applied alongside the PRISMA statement, which provides an evidence based minimum set of criteria for reporting systematic reviews and meta-analyses (Moher et al., 2009). While PRISMA provides a minimum, a process evaluation framework could assess underpinning theoretical

constructs, reported or potential barriers and facilitators to implementation and contextual variables. At present, there is no standard guidance for reporting on implementation in systematic reviews. The PRISMA guidelines for the reporting of systematic reviews of quantitative studies does not include instructions for reporting intervention implementation nor does its extension for the reporting of systematic reviews focusing on complex interventions, PRISMA-CI (Guise et al., 2017) (Flemming et al., 2018).

Process evaluation may learn from other approaches to the improvement of healthcare interventions. For example the Plan-Do-Study Act (PDSA) is a widely implemented structure for iterative testing of changes to improve quality of complex interventions. The 4-stage model is a cyclical learning approach, which plans, executes, studies and acts on changes in an iterative and constantly adapting cycle. It's possible that this highly adaptive approach could be beneficial to a process evaluation. However, the evidence base for PDSA is lacking and under-theorised and there is no formal framework (Taylor et al., 2014). Other approaches such as implementation science, which studies the use of strategies to adapt and use evidence based interventions in public health may offer insights on the translation of new interventions into practice (Lobb & Colditz, 2013); and it may be that quality improvement interventions can inform the best way to make use of limited resources in public health systems (Dilley, Bekemeier, & Harris, 2012).

Methodologies used to conduct process evaluation should also move beyond those identified in this thesis. For example, a process evaluation of an internet-delivered sexual health education intervention in The Netherlands used Google Analytics as a source of data on website visitor demographics, website traffic sources and content exposure. The authors concluded that Google Analytics provided useful quantitative data, which can be interpreted further using qualitative methods. This method of data collection involves minimal effort and could be valuable given the rate of expansion of internet-based interventions (Crutzen, Roosjen, & Poelman, 2013). Social media metrics may represent a further source of data, with application specific evaluation metrics encompassing 'reach' (the number of people who have been exposed to content) and 'engagement' (the number of people who have interacted with content rather than merely acknowledging it) (Neiger et al., 2012; Nguyen et al., 2013).

Future Challenges

A significant challenge for the researcher conducting a process evaluation is one of resources. Process evaluations require significant resources at every stage, demanding separate research studies be conducted alongside an already costly RCT. It is essential therefore that funding bodies are convinced of the enhanced explanatory power of process evaluations when allocating funding. Due to these resource limitations, a major challenge faced by researchers planning a process evaluation is the selection of process evaluation components for study. Researchers will rarely have the luxury of adequate resources to study each of the components outlined in this thesis, and so will need to prioritise. It is important for the development of the field that these decisions are stated and justified in process evaluation reports in the spirit of transparency. This will enable other researchers to fully understand the decision making process when designing and implementing a process evaluation, and to further their own understanding of process evaluation frameworks as a whole.

A further reason for limiting the components of process evaluation studied may be the vast amount of data yielded, which may not represent efficient use of resources. Qualitative studies in particular generate large amounts of data, and mixed methods analysis is time consuming (Klassen, Creswell, Plano Clark, Smith, & Meissner, 2012). Many researchers come from clinical healthcare positions which do not offer opportunities to develop the 'methodological bilingualism' necessary to conduct mixed methods research (Curry et al., 2009). Often, this type of research is secondary, or part of a PhD thesis. It takes longer than an RCT and funding may run out before it is completed. A process evaluation may also delay the reporting of the main trial findings.

Researchers should still make every effort to publish process evaluation findings, as at present there exists a trend for conducting process evaluations and reporting results as a single sentence within the main RCT publication. Separate publications will allow other researchers to replicate methods and contribute towards building a body of literature. Furthermore, it would promote the publication of qualitative research. At present, part of the problem is the reluctance of high impact journals to publish qualitative and/or mixed methods research papers (Greenhalgh et al., 2016).

Conclusion

This thesis reviewed existing frameworks and methods for conducting process evaluations; developed a theoretical framework for process evaluations of psychological interventions based on the review; described the extent to which an RCT of a psychological intervention in T2D evaluated underlying process and tested the face validity of a framework on a nurse-led psychological intervention, the D6 study.

The process evaluation yielded data on the implementation of a trial designed to target a specific group of patients within a primary care setting using a psychological therapy. The process evaluation revealed that the intervention was not implemented as intended; it revealed important barriers to implementation from the perspectives of both patients and providers, and the findings have implications for the design of future research. These data were even more important in light of the fact that the main intervention RCT results were non-significant.

What is clear from the results of this process evaluation, and the existing MRC guidance, is that process evaluation guidelines cannot be developed with a 'one size fits all approach'. The process evaluation reported in this thesis cannot offer speculation about what methods may work for other populations, in different settings. It may be that specific approaches best evaluate specific research designs. Although the CONSORT criteria for reporting of RCTs include assessment of trial generalisability, few trials include it, and a framework for empirically assessing and reporting it is lacking.

While the development of the framework reported in this thesis made an important contribution in scoping the history of process evaluation, identifying the core components of process evaluation and revealing the processes that contributed towards the null finding of the D6 intervention, more work is required. The framework was a useful starting point that was refined in light of testing and now requires further development, particularly on the synthesis of quantitative and qualitative methods.

The future of process evaluation research will be a constantly evolving field which should be highly iterative, whereby researchers test methodologies, theoretical concepts and techniques and, crucially, revise them, publishing findings and inviting discourse. Over the next 10 years, the field is likely to see rapid development in theoretical frameworks and consensus among researchers on constructs to include, and in turn we may see rapid development of more appropriate intervention designs, which can be replicated in the light of process evaluation findings. RCTs of interventions to improve outcome in T2D are reporting increasingly low effect sizes. Process evaluations are urgently needed to understand the reasons for this so that either we abandon this type of intervention or use the learning from process evaluation to innovate.

It is time to move beyond the idea that the binary yes or no answer provided by the RCT is sufficient. The complexity of healthcare interventions has had to develop to support the increasing challenges of managing long-term conditions, and our methods of evaluating them must keep up.

References

Abrams, D. B., Herzog, T. A., Emmons, K. M., & Linnan, L. (2000). Stages of change versus addiction: a replication and extension. *Nicotine & Tobacco Research, 2*(3), 223-229.

Ackermann, R. T., & Marrero, D. G. (2007). Adapting the Diabetes Prevention Program lifestyle intervention for delivery in the community. *The Diabetes Educator, 33*(1), 69-78.

Adolfsson, E. T., Smide, B., Gregeby, E., Fernström, L., & Wikblad, K. (2004). Implementing empowerment group education in diabetes. *Patient Education and Counseling, 53*(3), 319-324.

Adolfsson, E. T., Starrin, B., Smide, B., & Wikblad, K. (2008). Type 2 diabetic patients' experiences of two different educational approaches—A qualitative study. *International Journal of Nursing Studies, 45*(7), 986-994.

Adolfsson, E. T., Walker-Engström, M.-L., Smide, B., & Wikblad, K. (2007). Patient education in type 2 diabetes—a randomized controlled 1-year follow-up study. *Diabetes research and clinical practice, 76*(3), 341-350.

Aiken, L. H., Clarke, S. P., Sloane, D. M., Sochalski, J., & Silber, J. H. (2002). Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. *JAMA, 288*(16), 1987-1993.

Aikens, J., Kiolbasa, T., & Sobel, R. (1997). Psychological predictors of glycemic change with relaxation training in non-insulin-dependent diabetes mellitus. *Psychotherapy and psychosomatics, 66*(6), 302-306.

Alam, R., Sturt, J., Lall, R., & Winkley, K. (2009). An updated meta-analysis to assess the effectiveness of psychological interventions delivered by psychological specialists and generalist clinicians on glycaemic control and on psychological status. *Patient Education and Counseling, 75*(1), 25-36.

Ali, S., Stone, M., Peters, J., Davies, M., & Khunti, K. (2006). The prevalence of co‐morbid depression in adults with Type 2 diabetes: a systematic review and meta‐analysis. *Diabetic Medicine, 23*(11), 1165-1173.

Allison, K. C., Crow, S. J., Reeves, R. R., West, D. S., Foreyt, J. P., DiLillo, V. G., . . . Stunkard, A. J. (2007). Binge eating disorder and night eating syndrome in adults with type 2 diabetes. *Obesity, 15*(5), 1287-1293.

American Diabetes Association, D. M. (2014). Diagnosis and classification of diabetes mellitus. *Diabetes Care, 37*(Supplement 1), S81-S90.

Anderson, R. J., Freedland, K. E., Clouse, R. E., & Lustman, P. J. (2001). The Prevalence of Comorbid Depression in Adults With Diabetes. *A meta-analysis, 24*(6), 1069-1078. doi:10.2337/diacare.24.6.1069

Anderson, S., Allen, P., Peckham, S., & Goodwin, N. (2008). Asking the right questions: scoping studies in the commissioning of research on the organisation and delivery of health services. *Health research policy and systems, 6*(1), 7.

Andrews, R., Cooper, A., Montgomery, A., Norcross, A., Peters, T., Sharp, D., . . . Coulman, K. (2011). Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the Early ACTID randomised controlled trial. *The Lancet, 378*(9786), 129-139.

Apodaca, T. R., & Longabaugh, R. (2009). Mechanisms of change in motivational interviewing: A review and preliminary evaluation of the evidence. *Addiction, 104*(5), 705-715.
Arkes, H. R., Bar-Hillel, M., Beach, L. R., Brehmer, B., Brett, J. B., Castellan Jr, N. J., . . . Edwards, W. (1991). Organizational behavior and human decision processes.
Arkowitz, H. W., H A. (2004). Integrating Motivational Interviewing and Cognitive Behavioural Therapy in the Treatment of Depression and Anxiety *Journal of Cognitive Psychotherapy, 18*(4), 337-350.
Arksey, H., & O'Malley, L. (2005). Scoping studies: towards a methodological framework. *International journal of social research methodology, 8*(1), 19-32.
Ashcroft, R. E. (2004). Current epistemological problems in evidence based medicine. *Journal of Medical Ethics, 30*(2), 131-135.
Atkinson, M. A., Eisenbarth, G. S., & Michels, A. W. (2014). Type 1 diabetes. *The Lancet, 383*(9911), 69-82.
Attia, A. (2005). Bias in RCTs: confounders, selection bias and allocation concealment. *Middle East fertility society journal, 10*(3), 258.
Bandura, A. (2011). Social cognitive theory. *Handbook of social psychological theories, 2012*, 349-373.
Baranowski, T., & Stables, G. (2000). Process evaluations of the 5-a-day projects. *Health Education & Behavior, 27*(2), 157-166.
Barber, J. P., Sharpless, B. A., Klostermann, S., & McCarthy, K. S. (2007). Assessing intervention competence and its relation to therapy outcome: A selected review derived from the outcome literature. *Professional Psychology: Research and Practice, 38*(5), 493.
Barley, E. A., Walters, P., Tylee, A., & Murray, J. (2012). General practitioners' and practice nurses' views and experience of managing depression in coronary heart disease: a qualitative interview study. *BMC family practice, 13*(1), 1.
Barsky, A., & Coleman, H. (2001). Evaluating skill acquisition in motivational interviewing: The development of an instrument to measure practice skills. *Journal of Drug Education, 31*(1), 69-82.
Bartholomew, L. K., Parcel, G. S., & Kok, G. (1998). Intervention mapping: a process for developing theory and evidence-based health education programs. *Health Education & Behavior, 25*(5), 545-563.
Basch, C. E., Sliepcevich, E. M., Gold, R. S., Duncan, D. F., & Kolbe, L. J. (1985). Avoiding type III errors in health education program evaluations: a case study. *Health Education & Behavior, 12*(3), 315-331.
Batistatou, E., Roberts, C., & Roberts, S. (2014). Sample size and power calculations for trials and quasi-experimental studies with clustering. *Stata J, 14*(1), 159-175.
Beck, A. K., Baker, A., Britton, B., Wratten, C., Bauer, J., Wolfenden, L., & Carter, G. (2015). Fidelity considerations in translational research: Eating As Treatment—a stepped wedge, randomised controlled trial of a dietitian delivered behaviour change counselling intervention for head and neck cancer patients undergoing radiotherapy. *Trials, 16*(1), 1.
Beck, A. T. (1963). Thinking and depression: I. Idiosyncratic content and cognitive distortions. *Archives of general psychiatry, 9*(4), 324-333.
Beck, J. S. (2011). *Cognitive behavior therapy: Basics and beyond*: Guilford Press.

Begg, C., Cho, M., Eastwood, S., Horton, R., Moher, D., Olkin, I., . . . Simel, D. (1996). Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA, 276*(8), 637-639.

Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., . . . Czajkowski, S. (2004). Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23*(5), 443.

Bensing, J. (2000). Bridging the gap.: The separate worlds of evidence-based medicine and patient-centered medicine. *Patient Education and Counseling, 39*(1), 17-25.

Beresford, S. A., Shannon, J., McLerran, D., & Thompson, B. (2000). Seattle 5-a-day work-site project: process evaluation. *Health Education & Behavior, 27*(2), 213-222.

Berkowitz, J. M., Huhman, M., Heitzler, C. D., Potter, L. D., Nolin, M. J., & Banspach, S. W. (2008). Overview of formative, process, and outcome evaluation methods used in the VERB™ campaign. *American journal of preventive medicine, 34*(6), S222-S229.

Black, N. (1996). Why we need observational studies to evaluate the effectiveness of health care. *BMJ: British Medical Journal, 312*(7040), 1215.

Black, S. A., Markides, K. S., & Ray, L. A. (2003). Depression predicts increased incidence of adverse health outcomes in older Mexican Americans with type 2 diabetes. *Diabetes Care, 26*(10), 2822-2828.

Blackberry, I. D., Furler, J. S., Best, J. D., Chondros, P., Vale, M., Walker, C., . . . Audehm, R. (2013). Effectiveness of general practice based, practice nurse led telephone coaching on glycaemic control of type 2 diabetes: the Patient Engagement And Coaching for Health (PEACH) pragmatic cluster randomised controlled trial.

Blackburn, I.-M., James, I. A., Milne, D. L., Baker, C., Standart, S., Garland, A., & Reichelt, F. K. (2001). The revised cognitive therapy scale (CTS-R): psychometric properties. *Behavioural and Cognitive Psychotherapy, 29*(4), 431-446.

Blackwood, B., O'Halloran, P., & Porter, S. (2010). On the problems of mixing RCTs with qualitative research: the case of the MRC framework for the evaluation of complex healthcare interventions. *Journal of Research in Nursing, 15*(6), 511-521.

Blakely, C. H., Mayer, J. P., Gottschalk, R. G., Schmitt, N., Davidson, W. S., Roitman, D. B., & Emshoff, J. G. (1987). The fidelity‐adaptation debate: Implications for the implementation of public sector social programs. *American Journal of Community Psychology, 15*(3), 253-268.

Boehmk, S., Schlenk, E. A., Raleigh, E., & Ronis, D. (1993). Behavioral analysis and behavioral strategies to improve self-management of type II diabetes. *Clinical Nursing Research, 2*(3), 327-344.

Bond, G. R., Evans, L., Salyers, M. P., Williams, J., & Kim, H.-W. (2000). Measurement of fidelity in psychiatric rehabilitation. *Mental health services research, 2*(2), 75-87.

Bonell, C., Fletcher, A., Morton, M., Lorenc, T., & Moore, L. (2012). Realist randomised controlled trials: a new approach to evaluating complex public health interventions. *Social Science & Medicine, 75*(12), 2299-2306.

Bonell, C., Warren, E., Fletcher, A., & Viner, R. (2016). Realist trials and the testing of context-mechanism-outcome configurations: a response to Van Belle et al. *Trials, 17*(1), 478.
Booth, A., Hannes, K., Harden, A., Noyes, J., & Harris, J. (2014). COREQ (consolidated criteria for reporting qualitative studies).
Boruch, R. F., & Gomez, H. (1977). Sensitivity, bias, and theory in impact evaluations. *Professional Psychology, 8*(4), 411.
Boswell, J. F., Gallagher, M. W., Sauer-Zavala, S. E., Bullis, J., Gorman, J. M., Shear, M. K., . . . Barlow, D. H. (2013). Patient characteristics and variability in adherence and competence in cognitive-behavioral therapy for panic disorder. *Journal of consulting and clinical psychology, 81*(3), 443.
Boulé, N. G., Haddad, E., Kenny, G. P., Wells, G. A., & Sigal, R. J. (2001). Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. *JAMA, 286*(10), 1218-1227.
Boulton, A. J. (2005). Management of diabetic peripheral neuropathy. *Clinical diabetes, 23*(1), 9-15.
Bower, P., Cartwright, M., Hirani, S. P., Barlow, J., Hendy, J., Knapp, M., . . . Bardsley, M. (2011). A comprehensive evaluation of the impact of telemonitoring in patients with long-term conditions and social care needs: protocol for the whole systems demonstrator cluster randomised trial. *BMC Health Services Research, 11*(1), 184.
Bower, P., & Gilbody, S. (2005). Stepped care in psychological therapies: access, effectiveness and efficiency: narrative literature review. *The British Journal of Psychiatry, 186*(1), 11-17.
Braden, R. A. (1992). Formative Evaluation: A Revised Descriptive Theory and a Prescriptive Model.
Brandt, J., Spencer, M., & Folstein, M. (1988). The telephone interview for cognitive status. *Cognitive and Behavioral Neurology, 1*(2), 111-118.
Brannen, J. (2017). *Mixing methods: Qualitative and quantitative research*: Routledge.
Brehm, J. W. (1966). A theory of psychological reactance.
Breitenstein, S. M., Gross, D., Garvey, C. A., Hill, C., Fogg, L., & Resnick, B. (2010). Implementation fidelity in community‐based interventions. *Research in nursing & health, 33*(2), 164-173.
Brett, J. S., S; Mockfrod, C; Herron-Marx, S; Hughes, J; Tysall, C; Suleman, R. (2012). Mapping the impact of patient and public involvement on health and social care research: a systematic review. *Health Expectations, 17*(5), 637-650.
Britton, B., McCarter, K., Baker, A., Wolfenden, L., Wratten, C., Bauer, J., . . . Carter, G. (2015). Eating As Treatment (EAT) study protocol: a stepped-wedge, randomised controlled trial of a health behaviour change intervention provided by dietitians to improve nutrition in patients with head and neck cancer undergoing radiotherapy. *BMJ open, 5*(7), e008921.
Brobeck, E., Bergh, H., Odencrants, S., & Hildingh, C. (2011). Primary healthcare nurses' experiences with motivational interviewing in health promotion practice. *Journal of clinical nursing, 20*(23‐24), 3322-3330.
Brown, J. B., Harris, S. B., Webster-Bogaert, S., Wetmore, S., Faulds, C., & Stewart, M. (2002). The role of patient, physician and systemic factors in the management of type 2 diabetes mellitus. *Family Practice, 19*(4), 344-349.

Brown, S. A. (1992). Meta‐analysis of diabetes patient education research: Variations in intervention effects across studies. *Research in nursing & health, 15*(6), 409-419.

Browne, J. L., Ventura, A., Mosely, K., & Speight, J. (2013). 'I call it the blame and shame disease': a qualitative study about perceptions of social stigma surrounding type 2 diabetes. *BMJ open, 3*(11), e003384.

Browning, C., Chapman, A., Yang, H., Liu, S., Zhang, T., Enticott, J. C., & Thomas, S. A. (2016). Management of type 2 diabetes in China: the Happy Life Club, a pragmatic cluster randomised controlled trial using health coaches. *BMJ open, 6*(3), e009319.

Brug, J., Conner, M., Harre, N., Kremers, S., McKellar, S., & Whitelaw, S. (2004). The Transtheoretical Model and stages of change: a critique: observations by five commentators on the paper by Adams, J. and White, M.(2004) why don't stage-based activity promotion interventions work? *Health Education Research, 20*(2), 244-258.

Brunton, S. A., Davis, S. N., & Renda, S. M. (2006). Overcoming psychological barriers to insulin use in type 2 diabetes. *Clinical cornerstone, 8*, S19-S26.

Buller, D., Buller, M. K., Larkey, L., Sennott-Miller, L., Taren, D., Aickin, M., . . . Morrill, C. (2000). Implementing a 5-a-day peer health educator program for public sector labor and trades employees. *Health Education & Behavior, 27*(2), 232-240.

Burrus, B. B., Liburd, L. C., & Burroughs, A. (1998). Maximizing participation by black Americans in population-based diabetes research: the Project DIRECT pilot experience. *Journal of community health, 23*(1), 15-28.

Byng, R., Weaver, L., & Bury, C. (2002). GPs' beliefs about their management of depression and needs for supporting change in practice. *Primary Care Psychiatry, 8*(4), 121-126.

Calvert, M., Shankar, A., McManus, R. J., Lester, H., & Freemantle, N. (2009). Effect of the quality and outcomes framework on diabetes care in the United Kingdom: retrospective cohort study. *Bmj, 338*.

Campbell, D. T., & Fiske, D. W. (1959). Convergent and discriminant validation by the multitrait-multimethod matrix. *Psychological bulletin, 56*(2), 81.

Campbell, E. M., Redman, S., Moffitt, P., & Sanson-Fisher, R. W. (1996). The relative effectiveness of educational and behavioral instruction programs for patients with NIDDM: a randomized trial. *The Diabetes Educator, 22*(4), 379-386.

Campbell, L. V., Barth, R., Gosper, J. K., Jupp, J. J., Simons, L. A., & Chisholm, D. J. (1990). Impact of intensive educational approach to dietary change in NIDDM. *Diabetes Care, 13*(8), 841-847.

Campbell, M. K., Carr, C., DeVellis, B., Switzer, B., Biddle, A., Amamoo, M. A., . . . Sandler, R. (2009). A randomized trial of tailoring and motivational interviewing to promote fruit and vegetable consumption for cancer prevention and control. *Annals of Behavioral Medicine, 38*(2), 71-85.

Campbell, M. K., Motsinger, B. M., Ingram, A., Jewell, D., Makarushka, C., Beatty, B., . . . Demark-Wahnefried, W. (2000). The North Carolina Black Churches United for better health project: intervention and process evaluation. *Health Education & Behavior, 27*(2), 241-253.

Carey, J. W. (1993). Linking qualitative and quantitative methods: Integrating cultural factors into public health. *Qualitative Health Research, 3*(3), 298-318.

Carleton, R. A., Lasater, T. M., Assaf, A. R., Feldman, H. A., & McKinlay, S. (1995). The Pawtucket Heart Health Program: community changes in cardiovascular risk factors and projected disease risk. *American Journal of Public Health, 85*(6), 777-785.

Carlson, L. E., Ursuliak, Z., Goodey, E., Angen, M., & Speca, M. (2001). The effects of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients: 6-month follow-up. *Supportive care in Cancer, 9*(2), 112-123.

Carroll, C., Patterson, M., Wood, S., Booth, A., Rick, J., & Balain, S. (2007). A conceptual framework for implementation fidelity. *Implementation Science, 2*(1), 1.

Carroll, K. M., Farentinos, C., Ball, S. A., Crits-Christoph, P., Libby, B., Morgenstern, J., . . . Woody, G. E. (2002). MET meets the real world: design issues and clinical strategies in the Clinical Trials Network. *Journal of Substance Abuse Treatment, 23*(2), 73-80.

Carroll, K. M., Nich, C., Sifry, R. L., Nuro, K. F., Frankforter, T. L., Ball, S. A., . . . Rounsaville, B. J. (2000). A general system for evaluating therapist adherence and competence in psychotherapy research in the addictions. *Drug & Alcohol Dependence, 57*(3), 225-238.

Castaneda, C., Layne, J. E., Munoz-Orians, L., Gordon, P. L., Walsmith, J., Foldvari, M., . . . Nelson, M. E. (2002). A randomized controlled trial of resistance exercise training to improve glycemic control in older adults with type 2 diabetes. *Diabetes Care, 25*(12), 2335-2341.

Castelnuovo, G., Manzoni, G. M., Cuzziol, P., Cesa, G. L., Corti, S., Tuzzi, C., . . . Molinari, E. (2011). TECNOB study: ad interim results of a randomized controlled trial of a multidisciplinary telecare intervention for obese patients with type-2 diabetes. *Clinical Practice & Epidemiology in Mental Health, 7*(1).

Chao, J., Zong, M., Xu, H., Yu, Q., Jiang, L., Li, Y., . . . Liu, P. (2014). The long-term effect of community-based health management on the elderly with type 2 diabetes by the Markov modeling. *Archives of gerontology and geriatrics, 59*(2), 353-359.

Charman, D. (2000). Burnout and diabetes: reflections from working with educators and patients. *Journal of clinical psychology, 56*(5), 607-617.

Cheah, Y. H., D; Treasure, J; Ismail, K. (2008). Minutes of The 43rd General Assembly of The European Association for The Study of Diabetes. *Diabetologia, 51*(1), 1-588. doi:10.1007/s00125-008-1117-6

Chen, H.-T., & Rossi, P. H. (1989). Issues in the theory-driven perspective. *Evaluation and Program Planning, 12*(4), 299-306.

Chen, M.-F., Wang, R.-H., Lin, K.-C., Hsu, H.-Y., & Chen, S.-W. (2015). Efficacy of an empowerment program for Taiwanese patients with type 2 diabetes: A randomized controlled trial. *Applied Nursing Research, 28*(4), 366-373.

Chen, R., Ovbiagele, B., & Feng, W. (2016). Diabetes and stroke: epidemiology, pathophysiology, pharmaceuticals and outcomes. *The American journal of the medical sciences, 351*(4), 380-386.

Chen, S. M., Creedy, D., Lin, H.-S., & Wollin, J. (2012). Effects of motivational interviewing intervention on self-management, psychological and glycemic outcomes in type 2 diabetes: a randomized controlled trial. *International Journal of Nursing Studies, 49*(6), 637-644.

Chenail, R. J. (2011). Interviewing the investigator: Strategies for addressing instrumentation and researcher bias concerns in qualitative research. *Qualitative Report, 16*(1), 255-262.
Chisholm, D., Knapp, M. R. J., Knudsen, H. C., Amaddeo, F., Gaite, L., & Van Wijngaarden, B. (2000). Client Socio-Demographic and Service Receipt Inventory-European Version: development of an instrument for international research. *The British Journal of Psychiatry, 177*(39), s28-s33.
Chlebowy, D. O., El-Mallakh, P., Myers, J., Kubiak, N., Cloud, R., & Wall, M. P. (2014). Motivational interviewing to improve diabetes outcomes in African Americans adults with diabetes. *Western journal of nursing research*, 0193945914530522.
Cicchetti, D. V. (1994). Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychological assessment, 6*(4), 284.
Ciechanowski, P. S., Katon, W. J., & Russo, J. E. (2000a). Depression and diabetes: impact of depressive symptoms on adherence, function, and costs. *Archives of internal medicine, 160*(21), 3278-3285.
Ciechanowski, P. S., Katon, W. J., & Russo, J. E. (2000b). Depression and Diabetes: Impact of Depressive Symptoms on Adherence, Function, and Costs. *Arch Intern Med, 160*(21), 3278-3285. doi:10.1001/archinte.160.21.3278
Clark, M., Hampson, S. E., Avery, L., & Simpson, R. (2004). Effects of a tailored lifestyle self‐management intervention in patients with Type 2 diabetes. *British journal of health psychology, 9*(3), 365-379.
Clarke, G. N. (1995). Improving the transition from basic efficacy research to effectiveness studies: Methodological issues and procedures. *Journal of consulting and clinical psychology, 63*(5), 718.
Cochrane Collaboration, D. (2017). The Cochrane Database of Systematic Reviews. Retrieved from http://www.cochrane.org/
Cohen, M. Z., Tripp-Reimer, T., Smith, C., Sorofman, B., & Lively, S. (1994). Explanatory models of diabetes: Patient practitioner variation. *Social Science & Medicine, 38*(1), 59-66. doi:http://dx.doi.org/10.1016/0277-9536(94)90300-X
Cook, T. D., Campbell, D. T., & Day, A. (1979). *Quasi-experimentation: Design & analysis issues for field settings* (Vol. 351): Houghton Mifflin Boston.
Cooper, S. (1975). Hold the hardware: The use and abuse of tapes in clinical teaching and learning. *American Journal of Orthopsychiatry, 45*(4), 573.
Corbett, K., Thompson, B., White, N., & Taylor, M. (1990). Process evaluation in the community intervention trial for smoking cessation (COMMIT). *International Quarterly of Community Health Education, 11*(3), 291-309.
Corbie‐Smith, G., Thomas, S. B., Williams, M. V., & Moody‐Ayers, S. (1999). Attitudes and beliefs of African Americans toward participation in medical research. *Journal of general internal medicine, 14*(9), 537-546.
Corvino, J., Carroll, K., Nuro, K., Nich, C., Sifry, R., Frankforter, T., & Rounsaville, B. (2000). Yale adherence and competence scale guidelines. *West Haven, CT: Yale University Psychotherapy Development Center*.
Council, M. R. (2015). Training Courses in Trials and Methodology Retrieved from https://www.methodologyhubs.mrc.ac.uk/resources/training-courses/
Courtenay, M., & Carey, N. (2008). The impact and effectiveness of nurse‐led care in the management of acute and chronic pain: a review of the literature. *Journal of clinical nursing, 17*(15), 2001-2013.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj, 337*, a1655.

Creswell, J. W., & Clark, V. L. P. (2017). *Designing and conducting mixed methods research*: Sage publications.

Creswell, J. W., Plano Clark, V., & Hanson, W. (2003). Handbook of mixed methods in social and behavioral research. *Advanced mixed methods research designs, 209*.

Cross, W., & West, J. (2011). Examining implementer fidelity: Conceptualising and measuring adherence and competence. *Journal of children's services, 6*(1), 18-33.

Crutzen, R., Roosjen, J. L., & Poelman, J. (2013). Using Google Analytics as a process evaluation method for Internet-delivered interventions: an example on sexual health. *Health promotion international, 28*(1), 36-42.

Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care, 50*(3), 217.

Curry, L. A., Nembhard, I. M., & Bradley, E. H. (2009). Qualitative and mixed methods provide unique contributions to outcomes research. *Circulation, 119*(10), 1442-1452.

D'Eramo-Melkus, G. A., Wylie-Rosett, J., & Hagan, J. A. (1992). Metabolic impact of education in NIDDM. *Diabetes Care, 15*(7), 864-869.

Dane, A. V., & Schneider, B. H. (1998). Program integrity in primary and early secondary prevention: are implementation effects out of control? *Clinical psychology review, 18*(1), 23-45.

Das-Munshi, J., Stewart, R., Ismail, K., Bebbington, P. E., Jenkins, R., & Prince, M. J. (2007). Diabetes, common mental disorders, and disability: findings from the UK National Psychiatric Morbidity Survey. *Psychosomatic medicine, 69*(6), 543-550.

David, M., Cook Deborah, J., Susan, E., Ingram, O., & Drummond, R. (1994). Improving the Quality of Reporting of Meta-Analysis of Randomized Controlled Trials: The QUOROM statement. *Lancet, 354*, 1896-1900.

Davidoff, F., & Mooney, S. (2008). Publication guidelines for quality improvement studies in healthcare: evolution of the SQUIRE project. *Canadian Journal of Diabetes, 32*(4), 281-289.

Davidson, K., Scott, J., Schmidt, U., Tata, P., Thornton, S., & Tyrer, P. (2004). Therapist competence and clinical outcome in the Prevention of Parasuicide by Manual Assisted Cognitive Behaviour Therapy Trial: the POPMACT study. *Psychological medicine, 34*(5), 855-863.

Davies, M. J., Heller, S., Skinner, T. C., Campbell, M. J., Carey, M. E., Cradock, S., . . . Khunti, K. (2008). Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. *BMJ : British Medical Journal, 336*(7642), 491-495. doi:10.1136/bmj.39474.922025.BE

Davis, K., Drey, N., & Gould, D. (2009). What are scoping studies? A review of the nursing literature. *International Journal of Nursing Studies, 46*(10), 1386-1400.

Davis, M., Baranowski, T., Resnicow, K., Baranowski, J., Doyle, C., Smith, M., . . . Hebert, D. (2000). Gimme 5 fruit and vegetables for fun and health: process evaluation. *Health Education & Behavior, 27*(2), 167-176.

De Greef, K., Deforche, B., Tudor-Locke, C., & De Bourdeaudhuij, I. (2010). A cognitive-behavioural pedometer-based group intervention on physical activity and sedentary behaviour in individuals with type 2 diabetes. *Health Education Research, 25*(5), 724-736.

De Greef, K., Deforche, B., Tudor-Locke, C., & De Bourdeaudhuij, I. (2011). Increasing physical activity in Belgian type 2 diabetes patients: a three-arm randomized controlled trial. *International journal of behavioral medicine, 18*(3), 188-198.

De Groot, M., Anderson, R., Freedland, K. E., Clouse, R. E., & Lustman, P. J. (2001). Association of depression and diabetes complications: a meta-analysis. *Psychosomatic medicine, 63*(4), 619-630.

De Silva, M. J., Breuer, E., Lee, L., Asher, L., Chowdhary, N., Lund, C., & Patel, V. (2014). Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. *Trials, 15*(1), 267.

Deakin, T. (2011). The diabetes pandemic: is structured education the solution or an unnecessary expense? *Practical Diabetes, 28*(8), 1-14.

Deakin, T., Cade, J., Williams, R., & Greenwood, D. (2006). Structured patient education: the Diabetes X‐PERT Programme makes a difference. *Diabetic Medicine, 23*(9), 944-954.

Dehar, M.-A., Casswell, S., & Duignan, P. (1993). Formative and process evaluation of health promotion and disease prevention programs. *Evaluation Review, 17*(2), 204-220.

Dellasega, C., Añel-Tiangco, R. M., & Gabbay, R. A. (2012). How patients with type 2 diabetes mellitus respond to motivational interviewing. *Diabetes research and clinical practice, 95*(1), 37-41.

Department for Communities and Local Government. (2015). *The English Index of Multiple Deprivation (IMD) 2015 – Guidance*. Retrieved from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/464430/English_Index_of_Multiple_Deprivation_2015_-_Guidance.pdf.

DesprÉs, J.-p. (1997). 10 Visceral Obesity, Insulin Resistance, and Dyslipidemia: Contribution of Endurance Exercise Training to the Treatment of the Plurimetabolic Syndrome. *Exercise and sport sciences reviews, 25*(1), 271-300.

DiabetesUK. (2016a). Key Facts and Stats. Retrieved from https://www.diabetes.org.uk/Documents/Position statements/DiabetesUK_Facts_Stats_Oct16.pdf

DiabetesUK. (2016b). State of the Nation 2016 (England): time to take control of diabetes. Retrieved from https://www.diabetes.org.uk/Documents/Position statements/Diabetes UK State of the Nation 2016.pdf

DiClemente, C. C., & Prochaska, J. O. (1998). Toward a comprehensive, transtheoretical model of change: Stages of change and addictive behaviors.

Digital), H. a. S. C. I. C. N. (2016). Prescribing for Diabetes England 2005/06 to 2015/16. Retrieved from http://content.digital.nhs.uk/catalogue/PUB21158/pres-diab-eng-200506-201516.pdf

Dilley, J. A., Bekemeier, B., & Harris, J. R. (2012). Quality improvement interventions in public health systems: a systematic review. *American journal of preventive medicine, 42*(5), S58-S71.

DiMatteo, M. R. (2004). Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research. *Medical care, 42*(3), 200-209.

Dobson, D., & Cook, T. J. (1980). Avoiding type III error in program evaluation: Results from a field experiment. *Evaluation and Program Planning, 3*(4), 269-276.

Doherty, A. M., Gayle, C., Morgan-Jones, R., Archer, N., Laura-Lee, Ismail, K., & Werner, A. (2016). Improving quality of diabetes care by integrating psychological and social care for poorly controlled diabetes: 3 Dimensions of Care for Diabetes. *The International Journal of Psychiatry in Medicine, 51*(1), 3-15.

Donovan, J., Mills, N., Smith, M., Brindle, L., Jacoby, A., Peters, T., . . . Hamdy, F. (2002). Quality improvement report: Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. *BMJ: British Medical Journal*, 766-769.

Driscoll, D. L., Appiah-Yeboah, A., Salib, P., & Rupert, D. J. (2007). Merging qualitative and quantitative data in mixed methods research: How to and why not. *Ecological and Environmental Anthropology (University of Georgia)*, 18.

Dusenbury, L., Brannigan, R., Falco, M., & Hansen, W. B. (2003). A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Education Research, 18*(2), 237-256.

Dusenbury, L., Hansen, W. B., Jackson-Newsom, J., Pittman, D. S., Wilson, C. V., Nelson-Simley, K., . . . Giles, S. M. (2010). Coaching to enhance quality of implementation in prevention. *Health Education, 110*(1), 43-60.

Eakin, E. G., Winkler, E. A., Dunstan, D. W., Healy, G. N., Owen, N., Marshall, A. M., . . . Reeves, M. M. (2014). Living well with diabetes: 24-month outcomes from a randomized trial of telephone-delivered weight loss and physical activity intervention to improve glycemic control. *Diabetes Care, 37*(8), 2177-2185.

Egede, L. E., & Zheng, D. (2003). Independent factors associated with major depressive disorder in a national sample of individuals with diabetes. *Diabetes Care, 26*(1), 104-111.

Elford, J., Sherr, L., Bolding, G., Serle, F., & Maguire, M. (2002). Peer-led HIV prevention among gay men in London: process evaluation. *AIDS care, 14*(3), 351-360.

Engelgau, M. M., Narayan, K., Geiss, L. S., Thompson, T. J., Beckles, G., Lopez, L., . . . Liburd, L. (1998). A project to reduce the burden of diabetes in the African-American Community: Project DIRECT. *Journal of the National Medical Association, 90*(10), 605.

Espie, C. A., Macmahon, K. M., Kelly, H.-L., Broomfield, N. M., Douglas, N. J., Engleman, H. M., . . . Wilson, P. (2007). Randomized clinical effectiveness trial of nurse-administered small-group cognitive behavior therapy for persistent insomnia in general practice. *sleep, 30*(5), 574-584.

Evans, R., Scourfield, J., & Murphy, S. (2014). The unintended consequences of targeted interventions: Young people's lived experiences of targeted social and emotional learning interventions. *Br Educ Res J*.

Evans, R., Scourfield, J., & Murphy, S. (2015). Pragmatic, formative process evaluations of complex interventions and why we need more of them: BMJ Publishing Group Ltd.
Evans, R. I., Raines, B. E., & Owen, A. E. (1989). Formative evaluation in school-based health promotion investigations. *Preventive Medicine, 18*(2), 229-234.
Fairweather, G. W., & Tornatzky, L. G. (2013). *Experimental Methods for Social Policy Research: Pergamon International Library of Science, Technology, Engineering and Social Studies* (Vol. 69): Elsevier.
Fan, L., & Sidani, S. (2009). Effectiveness of diabetes self-management education intervention elements: a meta-analysis. *Canadian Journal of Diabetes, 33*(1), 18-26.
Farquhar, J. W., Fortmann, S. P., Flora, J. A., Taylor, C. B., Haskell, W. L., Williams, P. T., . . . Wood, P. D. (1990). Effects of communitywide education on cardiovascular disease risk factors: the Stanford Five-City Project. *JAMA, 264*(3), 359-365.
Farquhar, J. W., Fortmann, S. P., Maccoby, N., Haskell, W. L., Williams, P. T., Flora, J. A., . . . Hulley, S. B. (1985). The Stanford five-city project: design and methods. *American Journal of Epidemiology, 122*(2), 323-334.
Faulkner, A. (2006). Beyond our expectations: A report of the experiences of involving service users in forensic mental health research. *National Programme on Forensic Mental Health R&D. London: Department of Health*.
Feinstein, A. R., & Horwitz, R. I. (1997). Problems in the "evidence" of "evidence-based medicine". *The American journal of medicine, 103*(6), 529-535.
Ferlie, E. B., & Shortell, S. M. (2001). Improving the quality of health care in the United Kingdom and the United States: a framework for change. *Milbank Quarterly, 79*(2), 281-315.
Festinger, L. (1962). *A theory of cognitive dissonance* (Vol. 2): Stanford university press.
Fetters, M. D., Curry, L. A., & Creswell, J. W. (2013). Achieving integration in mixed methods designs—principles and practices. *Health services research, 48*(6pt2), 2134-2156.
Firth-Cozens, J. (2001). Interventions to improve physicians' well-being and patient care. *Social Science & Medicine, 52*(2), 215-222.
Fisher, L., Glasgow, R. E., & Strycker, L. A. (2010). The relationship between diabetes distress and clinical depression with glycemic control among patients with type 2 diabetes. *Diabetes Care, 33*(5), 1034-1036.
Fisher, L., Skaff, M. M., Mullan, J. T., Arean, P., Mohr, D., Masharani, U., . . . Laurencin, G. (2007). Clinical depression versus distress among patients with type 2 diabetes: not just a question of semantics. *Diabetes Care, 30*(3), 542-548.
Fitzpatrick, J. L. (1988). Roles of the evaluator in innovative programs: A formative evaluation. *Evaluation Review, 12*(4), 449-461.
Fixsen, D. L., & Blase, K. A. (1993). Creating new realities: Program development and dissemination. *Journal of Applied Behavior Analysis, 26*(4), 597-615.
Fixsen, D. L., Naoom, S. F., Blase, K. A., & Friedman, R. M. (2005). Implementation research: a synthesis of the literature.
Flemming, K., Booth, A., Hannes, K., Cargo, M., & Noyes, J. (2018). Cochrane Qualitative and Implementation Methods Group guidance series—paper 6: reporting guidelines for qualitative, implementation, and process evaluation evidence syntheses. *Journal of clinical epidemiology, 97*, 79-85.

Fletcher, G. J. (1996). Realism versus relativism in psychology. *The American journal of psychology*, 409-429.
Forsberg, L., Forsberg, L. G., Lindqvist, H., & Helgason, A. R. (2010). Clinician acquisition and retention of Motivational Interviewing skills: a two-and-a-half-year exploratory study. *Substance Abuse Treatment, Prevention, and Policy, 5*(1), 8. doi:10.1186/1747-597x-5-8
Foundation, T. H. Co-Creating Health. Retrieved from http://www.health.org.uk/programmes/co-creating-health
Freedland, K. E., Mohr, D. C., Davidson, K. W., & Schwartz, J. E. (2011). Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. *Psychosomatic medicine, 73*(4), 323.
French, D., Wade, A., Yudkin, P., Neil, H., Kinmonth, A., & Farmer, A. (2008). Self‐monitoring of blood glucose changed non‐insulin‐treated Type 2 diabetes patients' beliefs about diabetes and self‐monitoring in a randomized trial. *Diabetic Medicine, 25*(10), 1218-1228.
Furler, J., Walker, C., Blackberry, I., Dunning, T., Sulaiman, N., Dunbar, J., . . . Young, D. (2008). The emotional context of self-management in chronic illness: a qualitative study of the role of health professional support in the self-management of type 2 diabetes. *BMC Health Services Research, 8*(1), 1.
Gabbay, R. A., Añel‐Tiangco, R. M., Dellasega, C., Mauger, D. T., Adelman, A., & Van Horn, D. H. (2013). Diabetes nurse case management and motivational interviewing for change (DYNAMIC): Results of a 2‐year randomized controlled pragmatic trial (糖尿病□士病例管理以及促□改□的□机性会□（DYNAMIC）：一□□期 2 年的□用随机□照研究). *Journal of diabetes, 5*(3), 349-357.
Gæde, P., Vedel, P., Parving, H.-H., & Pedersen, O. (1999). Intensified multifactorial intervention in patients with type 2 diabetes mellitus and microalbuminuria: the Steno type 2 randomised study. *The Lancet, 353*(9153), 617-622.
Gale, L., Vedhara, K., Searle, A., Kemple, T., & Campbell, R. (2008). Patients' perspectives on foot complications in type 2 diabetes: a qualitative study. *British Journal of General Practice, 58*(553), 555-563. doi:10.3399/bjgp08X319657
Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC medical research methodology, 13*(1), 117.
Gan, D. (2003). *Diabetes atlas*: International Diabetes Federation.
García-Huidobro, D., Bittner, M., Brahm, P., & Puschel, K. (2011). Family intervention to control type 2 diabetes: a controlled clinical trial. *Family Practice, 28*(1), 4-11.
Garfield, S. A., Malozowski, S., Chin, M. H., Narayan, K. V., Glasgow, R. E., Green, L. W., . . . Krumholz, H. M. (2003). Considerations for diabetes translational research in real-world settings. *Diabetes Care, 26*(9), 2670-2674.
Gelo, O., Braakmann, D., & Benetka, G. (2008). Quantitative and qualitative research: Beyond the debate. *Integrative psychological and behavioral science, 42*(3), 266-290.
Glasgow, R. E., & Emmons, K. M. (2007). How can we increase translation of research into practice? Types of evidence needed. *Annu. Rev. Public Health, 28*, 413-433.

Glasgow, R. E., Klesges, L. M., Dzewaltowski, D. A., Bull, S. S., & Estabrooks, P. (2004). The future of health behavior change research: what is needed to improve translation of research into health promotion practice? *Annals of Behavioral Medicine, 27*(1), 3-12.

Glasgow, R. E., Lichtenstein, E., & Marcus, A. C. (2003). Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *American Journal of Public Health, 93*(8), 1261-1267.

Glasgow, R. E., Toobert, D. J., & Gillette, C. D. (2001). Psychosocial barriers to diabetes self-management and quality of life. *Diabetes spectrum, 14*(1), 33-41.

Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American Journal of Public Health, 89*(9), 1322-1327.

Glass, G. V. (1976). Primary, Secondary, and Meta-Analysis of Research 1. *Educational researcher, 5*(10), 3-8.

Glasziou, P., Chalmers, I., Altman, D. G., Bastian, H., Boutron, I., Brice, A., . . . Groves, T. (2010). Taking healthcare interventions from trial to practice. *Bmj, 341*, c3852.

Goode, A. D., Winkler, E. A., Reeves, M. M., & Eakin, E. G. (2015). Relationship between intervention dose and outcomes in living well with diabetes—a randomized trial of a telephone-delivered lifestyle-based weight loss intervention. *American Journal of Health Promotion, 30*(2), 120-129.

Grafton, J., Lillis, A. M., Malina, M. A., Nørreklit, H. S., & Selto, F. H. (2011). Lessons learned: advantages and disadvantages of mixed method research. *Qualitative Research in Accounting & Management, 8*(1), 59-71.

Grant, A., Treweek, S., Dreischulte, T., Foy, R., & Guthrie, B. (2013). Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials, 14*(1), 1.

Grant, M. J., & Booth, A. (2009). A typology of reviews: an analysis of 14 review types and associated methodologies. *Health Information & Libraries Journal, 26*(2), 91-108.

Graves, H., Garrett, C., Amiel, S. A., Ismail, K., & Winkley, K. (2016). Psychological skills training to support diabetes self-management: Qualitative assessment of nurses' experiences. *Primary care diabetes, 10*(5), 376-382.

Gray, R., Parr, A. M., Plummer, S., Sandford, T., Ritter, S., Mundt‐Leach, R., . . . Gournay, K. (1999). A national survey of practice nurse involvement in mental health interventions. *Journal of advanced nursing, 30*(4), 901-906.

Green, J. (2000). The role of theory in evidence-based health promotion practice: Oxford Univ Press.

Green, L. W. (1977). Evaluation and measurement: some dilemmas for health education. *American Journal of Public Health, 67*(2), 155-161.

Greenhalgh, T., Annandale, E., Ashcroft, R., Barlow, J., Black, N., Bleakley, A., . . . Carnevale, F. (2016). An open letter to The BMJ editors on qualitative research. *Bmj, 352*(i563).

Griffin, S., Kinmonth, A., Skinner, C., & Kelly, J. (1999). Educational and psychosocial interventions for adults with diabetes. *London: British Diabetic Association*.

Grigsby, A. B., Anderson, R. J., Freedland, K. E., Clouse, R. E., & Lustman, P. J. (2002). Prevalence of anxiety in adults with diabetes: a systematic review. *Journal of psychosomatic research, 53*(6), 1053-1060.

Group, D. P. P. R. (2002). The diabetes prevention program (DPP). *Diabetes Care, 25*(12), 2165-2171.
Guba, E. G., & Lincoln, Y. S. (1985). Naturalistic inquiry: Newbury Park, CA: Sage.
Guise, J.-M., Butler, M. E., Chang, C., Viswanathan, M., Pigott, T., Tugwell, P., & Workgroup, C. I. (2017). AHRQ series on complex intervention systematic reviews—paper 6: PRISMA-CI extension statement and checklist. *Journal of clinical epidemiology, 90*, 43-50.
Gulliford, M. C., Naithani, S., & Morgan, M. (2007). Continuity of care and intermediate outcomes of type 2 diabetes mellitus. *Family Practice, 24*(3), 245-251.
Gülmezoglu, A. M., Chandler, J., Shepperd, S., & Pantoja, T. (2013). Reviews of qualitative evidence: a new milestone for Cochrane. *Cochrane Database of Systematic Reviews*(11).
Haddock, G., Barrowclough, C., Tarrier, N., Moring, J., O'BRIEN, R., Schofield, N., . . . Lowens, I. (2003). Cognitive–behavioural therapy and motivational intervention for schizophrenia and substance misuse. *The British Journal of Psychiatry, 183*(5), 418-426.
Hanley, B., Truesdale, A., King, A., Elbourne, D., & Chalmers, I. (2001). Involving consumers in designing, conducting, and interpreting randomised controlled trials: questionnaire survey. *Bmj, 322*(7285), 519-523.
Hansen, N. B., Lambert, M. J., & Forman, E. M. (2002). The psychotherapy dose‐response effect and its implications for treatment delivery services. *Clinical Psychology: Science and Practice, 9*(3), 329-343.
Hardeman, W., Lamming, L., Kellar, I., De Simoni, A., Graffy, J., Boase, S., . . . Kinmonth, A. L. (2014). Implementation of a nurse-led behaviour change intervention to support medication taking in type 2 diabetes: beyond hypothesised active ingredients (SAMS Consultation Study). *Implement Sci, 9*, 70. doi:10.1186/1748-5908-9-70
Hardy, C., Phillips, N., & Clegg, S. (2001). Reflexivity in organization and management theory: a study of the production of the researchsubject'. *Human relations, 54*(5), 531-560.
Hargreaves, J., Hatcher, A., Strange, V., Phetla, G., Busza, J., Kim, J., . . . Pronyk, P. (2010). Process evaluation of the Intervention with Microfinance for AIDS and Gender Equity (IMAGE) in rural South Africa. *Health Education Research, 25*(1), 27-40.
Harkness, E., Macdonald, W., Valderas, J., Coventry, P., Gask, L., & Bower, P. (2010). Identifying psychosocial interventions that improve both physical and mental health in patients with diabetes. *Diabetes Care, 33*(4), 926-930.
Hartmann, M., Kopf, S., Kircher, C., Faude-Lang, V., Djuric, Z., Augstein, F., . . . Humpert, P. M. (2012). Sustained effects of a mindfulness-based stress-reduction intervention in type 2 diabetic patients design and first results of a randomized controlled trial (the Heidelberger diabetes and stress-study). *Diabetes Care, 35*(5), 945-947.
Hartwell, S. L., Kaplan, R. M., & Wallace, J. P. (1986). Comparison of behavioral interventions for control of type II diabetes mellitus. *Behavior Therapy, 17*(4), 447-461.
Hassan, H. A., Tohid, H., Amin, R. M., Bidin, M. B. L., Muthupalaniappen, L., & Omar, K. (2013). Factors influencing insulin acceptance among type 2 diabetes mellitus patients in a primary care clinic: a qualitative exploration. *BMC family practice, 14*(1), 164.

Hasson, H. (2010). Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implementation Science, 5*(1), 67.
Havas, S., Anliker, J., Damron, D., Feldman, R., & Langenberg, P. (2000). Uses of process evaluation in the Maryland WIC 5-a-day promotion program. *Health Education & Behavior, 27*(2), 254-263.
Health, D. o. (2010). *Equity and excellence:: liberating the NHS* (Vol. 7881): The Stationery Office.
Heinrich, E., Candel, M. J., Schaper, N. C., & de Vries, N. K. (2010). Effect evaluation of a Motivational Interviewing based counselling strategy in diabetes care. *Diabetes research and clinical practice, 90*(3), 270-278.
Heinrich, E., Schaper, N. C., & de Vries, N. K. (2015). Self-management interventions for type 2 diabetes: a systematic review. *European Diabetes Nursing*.
Heisler, M., Vijan, S., Makki, F., & Piette, J. D. (2010). Diabetes control with reciprocal peer support versus nurse care management: a randomized trial. *Annals of internal medicine, 153*(8), 507-515.
Heitzmann, C. A., Kaplan, R. M., Wilson, D. K., & Sandler, J. (1987). Sex differences in weight loss among adults with type II diabetes mellitus. *Journal of behavioral medicine, 10*(2), 197-211.
Helitzer, D. L., Davis, S. M., Gittelsohn, J., Going, S. B., Murray, D. M., Snyder, P., & Steckler, A. B. (1999). Process evaluation in a multisite, primary obesity-prevention trial in American Indian schoolchildren. *The American journal of clinical nutrition, 69*(4), 816S-824S.
Henry, J. L., Wilson, P. H., Bruce, D., Chisholm, D., & Rawling, P. (1997). Cognitive-behavioural stress management for patients with non-insulin dependent diabetes mellitus. *Psychology, Health & Medicine, 2*(2), 109-118.
Herpertz, S., Albus, C., Lichtblau, K., Köhle, K., Mann, K., & Senf, W. (2000). Relationship of weight and eating disorders in type 2 diabetic patients: a multicenter study. *International Journal of Eating Disorders, 28*(1), 68-77.
Herpertz, S., Albus, C., Wagener, R., Kocnar, M., Wagner, R., Henning, A., . . . Senf, W. (1998). Comorbidity of Diabetes and Eating Disorders: Does diabetes control reflect disturbed eating behavior? *Diabetes Care, 21*(7), 1110-1116. doi:10.2337/diacare.21.7.1110
Hess, L. M., Raebel, M. A., Conner, D. A., & Malone, D. C. (2006). Measurement of adherence in pharmacy administrative databases: a proposal for standard definitions and preferred measures. *Annals of pharmacotherapy, 40*(7-8), 1280-1288.
Hettema, J., Steele, J., & Miller, W. R. (2005). Motivational interviewing. *Annu. Rev. Clin. Psychol., 1*, 91-111.
Higgins, J., & Wells, G. (2011). Cochrane handbook for systematic reviews of interventions.
Hill-Briggs, F., Lazo, M., Peyrot, M., Doswell, A., Chang, Y.-T., Hill, M. N., . . . Brancati, F. L. (2011). Effect of problem-solving-based diabetes self-management training on diabetes control in a low income patient sample. *Journal of general internal medicine, 26*(9), 972-978.
Hinchliffe, R., Jeffcoate, W., & Game, F. (2006). Diabetes, established renal failure and the risk to the lower limb. *Practical Diabetes, 23*(1), 28-32.
Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., . . . Johnston, M. (2014). Better reporting of interventions: template for

intervention description and replication (TIDieR) checklist and guide. *Bmj, 348*, g1687.
Hollon, S., Evans, M., Auerbach, A., DeRubeis, R., Elkin, I., Lowery, A., . . . Piasecki, J. (1988). Development of a system for rating therapies for depression: Differentiating cognitive therapy, interpersonal psychotherapy, and clinical management pharmacotherapy. *Unpublished manuscript*.
Holman, R. R., Paul, S. K., Bethel, M. A., Matthews, D. R., & Neil, H. A. W. (2008). 10-year follow-up of intensive glucose control in type 2 diabetes. *New England Journal of Medicine, 359*(15), 1577-1589.
Hornik, R. (1980). Shedding some light on evaluation's myths. *Dev Commun Rep, 29*, 1-4.
Hoskin, K. (1979). The examination, disciplinary power and rational schooling. *History of Education, 8*(2), 21-135.
Houghton, C., Casey, D., Shaw, D., & Murphy, K. (2013). Rigour in qualitative case-study research. *Nurse researcher, 20*(4).
HSCIC. (2012). *Report into the data quality of Diabetes Structured Education*. Retrieved from
Huang, C.-Y., Lai, H.-L., Chen, C.-I., Lu, Y.-C., Li, S.-C., Wang, L.-W., & Su, Y. (2016). Effects of motivational enhancement therapy plus cognitive behaviour therapy on depressive symptoms and health-related quality of life in adults with type II diabetes mellitus: a randomised controlled trial. *Quality of Life Research, 25*(5), 1275-1283.
Hunt, L. M., Valenzuela, M. A., & Pugh, J. A. (1997). NIDDM Patients' Fears and Hopes About Insulin Therapy: The basis of patient reluctance. *Diabetes Care, 20*(3), 292-298. doi:10.2337/diacare.20.3.292
Hunt, M. K., Lederman, R., Potter, S., Stoddard, A., & Sorensen, G. (2000). Results of employee involvement in planning and implementing the Treatwell 5-a-Day work-site study. *Health Education & Behavior, 27*(2), 223-231.
Hurlburt, M. S., Garland, A. F., Nguyen, K., & Brookman-Frazee, L. (2010). Child and family therapy process: Concordance of therapist and observational perspectives. *Administration and Policy in Mental Health and Mental Health Services Research, 37*(3), 230-244.
Ismail, K., Maissi, E., Thomas, S., Chalder, T., Schmidt, U., Bartlett, J., . . . Treasure, J. (2010). A randomised controlled trial of cognitive behaviour therapy and motivational interviewing for people with type I diabetes mellitus with persistent sub-optimal glycaemic control: A Diabetes and Psychological Therapies (ADaPT) study. *Health technology assessment (Winchester, England), 14*(22), 1-+.
Ismail, K., Thomas Sm Fau - Maissi, E., Maissi E Fau - Chalder, T., Chalder T Fau - Schmidt, U., Schmidt U Fau - Bartlett, J., Bartlett J Fau - Patel, A., . . . Treasure, J. (2008a). Motivational enhancement therapy with and without cognitive behavior therapy to treat type 1 diabetes: a randomized trial. (1539-3704 (Electronic)).
Ismail, K., Thomas, S. M., Maissi, E., Chalder, T., Schmidt, U., Bartlett, J., . . . Treasure, J. (2008b). Motivational Enhancement Therapy with and without Cognitive Behavior Therapy to Treat Type 1 Diabetes. *Annals of Internal Medicine, 149*(10), 708-719.
Ismail, K., Winkley, K., Daniel, S., Chalder, T., & Edmonds, M. (2006). *Depressive disorders, diabetic foot ulcers and death: results from a population based*

cohort of people with diabetes and their first foot ulcer. Paper presented at the Diabetologia.

Ismail, K., Winkley K Fau - Rabe-Hesketh, S., & Rabe-Hesketh, S. Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. (1474-547X (Electronic)).

Ismail, K., Winkley K Fau - Rabe-Hesketh, S., & Rabe-Hesketh, S. (2004). Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. (1474-547X (Electronic)).

Ismail, K., Winkley, K., & Rabe-Hesketh, S. Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. *The Lancet, 363*(9421), 1589-1597. doi:10.1016/S0140-6736(04)16202-8

Israel, B. A., Cummings, K. M., Dignan, M. B., Heaney, C. A., Perales, D. P., Simons-Morton, B. G., & Zimmerman, M. A. (1995). Evaluation of health education programs: current assessment and future directions. *Health education quarterly, 22*(3), 364-389.

Jablon, S. L., Naliboff, B. D., Gilmore, S. L., & Rosenthal, M. J. (1997). Effects of relaxation training on glucose tolerance and diabetic control in type II diabetes. *Applied psychophysiology and biofeedback, 22*(3), 155-169.

Jadad, A. (1998). *Randomised controlled trials*: BMJ London.

Jallinoja, P., Absetz, P., Kuronen, R., Nissinen, A., Talja, M., Uutela, A., & Patja, K. (2007). The dilemma of patient responsibility for lifestyle change: perceptions among primary care physicians and nurses. *Scandinavian journal of primary health care, 25*(4), 244-249.

Jamal, F., Fletcher, A., Shackleton, N., Elbourne, D., Viner, R., & Bonell, C. (2015). The three stages of building and testing mid-level theories in a realist RCT: a theoretical and methodological case-example. *Trials, 16*(1), 466.

Jansink, R., Braspenning, J., Keizer, E., van der Weijden, T., Elwyn, G., & Grol, R. (2013). No identifiable Hb1Ac or lifestyle change after a comprehensive diabetes programme including motivational interviewing: a cluster randomised trial. *Scandinavian journal of primary health care, 31*(2), 119-127.

Jansink, R., Braspenning, J., van der Weijden, T., Elwyn, G., & Grol, R. (2010). Primary care nurses struggle with lifestyle counseling in diabetes care: a qualitative analysis. *BMC family practice, 11*(1), 1.

Jick, T. D. (1979). Mixing qualitative and quantitative methods: Triangulation in action. *Administrative science quarterly, 24*(4), 602-611.

Johnsen, M., Samberg, L., Calsyn, R., Blasinsky, M., Landow, W., & Goldman, H. (1999). Case management models for persons who are homeless and mentally ill: The ACCESS demonstration project. *Community Mental Health Journal, 35*(4), 325-346.

Johnson, B., & Turner, L. A. (2003). Data collection strategies in mixed methods research. *Handbook of mixed methods in social and behavioral research*, 297-319.

Jonkers, C., Lamers, F., Bosma, H., Metsemakers, J., Kempen, G., & Van Eijk, J. (2007). Process evaluation of a minimal psychological intervention to reduce depression in chronically ill elderly persons. *Patient Education and Counseling, 68*(3), 252-257.

Kane, R. A. (2001). Long-term care and a good quality of life bringing them closer together. *The Gerontologist, 41*(3), 293-304.
Kaslow, N. J., & Keilin, W. G. (2006). Internship training in clinical psychology: Looking into our crystal ball. *Clinical Psychology: Science and Practice, 13*(3), 242-248.
Kasteleyn, M., Vos, R., Rijken, M., Schellevis, F., & Rutten, G. (2016). Effectiveness of tailored support for people with Type 2 diabetes after a first acute coronary event: a multicentre randomized controlled trial (the Diacourse‐ACE study). *Diabetic Medicine, 33*(1), 125-133.
Katon, W., Von Korff, M., Lin, E., & Simon, G. (2001). Rethinking practitioner roles in chronic illness: the specialist, primary care physician, and the practice nurse. *Gen Hosp Psychiatry, 23*(3), 138-144.
Katon, W. J., Rutter, C., Simon, G., Lin, E. H., Ludman, E., Ciechanowski, P., . . . Von Korff, M. (2005). The association of comorbid depression with mortality in patients with type 2 diabetes. *Diabetes Care, 28*(11), 2668-2672.
Kaushal, R., Shojania, K. G., & Bates, D. W. (2003). Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review. *Archives of internal medicine, 163*(12), 1409-1416.
Kazantzis, N. (2003). Therapist competence in cognitive-behavioural therapies: Review of the contemporary empirical evidence. *Behaviour Change, 20*(1), 1-12.
Keeratiyutawong, P., Hanucharurnkul, S., Melkus, G. E., Panpakdee, O., & Vorapongsathorn, T. (2006). Effectiveness of a self-management program for Thais with type 2 diabetes. *Thai Journal of Nursing Research, 10*(2), 85-97.
Kegeles, S. M., Hays, R. B., & Coates, T. J. (1996). The Mpowerment Project: a community-level HIV prevention intervention for young gay men. *American Journal of Public Health, 86*(8_Pt_1), 1129-1136.
Kellaghan, T., & Madaus, G. F. (1982). Trends in educational standards in Great Britain and Ireland. *The rise and fall of national test scores*, 195-214.
Kelly, J. A., Heckman, T. G., Stevenson, L. Y., & Williams, P. N. (2000). Transfer of research-based HIV prevention interventions to community service providers: fidelity and adaptation. *AIDS Education and Prevention, 12*, 87.
Kenardy, J., Mensch, M., Bowen, K., Green, B., & Walton, J. (2002). Group therapy for binge eating in type 2 diabetes: a randomized trial. *Diabetic Medicine, 19*(3), 234-239.
Kenardy, J., Mensch, M., Bowen, K., Green, B., Walton, J., & Dalton, M. (2001). Disordered eating behaviours in women with Type 2 diabetes mellitus. *Eating Behaviors, 2*(2), 183-192. doi:http://dx.doi.org/10.1016/S1471-0153(01)00028-9
Kennedy, T., Jones, R., Darnley, S., Seed, P., Wessely, S., & Chalder, T. (2005). Cognitive behaviour therapy in addition to antispasmodic treatment for irritable bowel syndrome in primary care: randomised controlled trial. *Bmj, 331*(7514), 435.
Keogh, K. M., Smith, S. M., White, P., McGilloway, S., Kelly, A., Gibney, J., & O'Dowd, T. (2011). Psychological family intervention for poorly controlled type 2 diabetes. *The American journal of managed care, 17*(2), 105-113.
Keogh, K. M., White P Fau - Smith, S. M., Smith Sm Fau - McGilloway, S., McGilloway S Fau - O'Dowd, T., O'Dowd T Fau - Gibney, J., & Gibney, J. (2007). Changing illness perceptions in patients with poorly controlled type 2

diabetes, a randomised controlled trial of a family-based intervention: protocol and pilot study. (1471-2296 (Electronic)). doi:D - NLM: PMC1919379 EDAT- 2007/06/29 09:00 MHDA- 2007/08/19 09:00 CRDT- 2007/06/29 09:00 PHST- 2007/05/17 [received] PHST- 2007/06/27 [accepted] PHST- 2007/06/27 [aheadofprint] AID - 1471-2296-8-36 [pii] AID - 10.1186/1471-2296-8-36 [doi] PST - epublish

Keogh-Brown, M., Bachmann, M., Shepstone, L., Hewitt, C., Howe, A., Ramsay, C. R., . . . Miles, S. (2007). Contamination in trials of educational interventions.

Khan, H., Lasker, S. S., & Chowdhury, T. A. (2011). Exploring reasons for very poor glycaemic control in patients with Type 2 diabetes. *Primary care diabetes, 5*(4), 251-255.

Khan, K. S., Ter Riet, G., Glanville, J., Sowden, A. J., & Kleijnen, J. (2001). *Undertaking systematic reviews of research on effectiveness: CRD's guidance for carrying out or commissioning reviews*: NHS Centre for Reviews and Dissemination.

Khattab, M., Khader, Y. S., Al-Khawaldeh, A., & Ajlouni, K. (2010). Factors associated with poor glycemic control among patients with type 2 diabetes. *Journal of Diabetes and its Complications, 24*(2), 84-89.

Khunti, K., Gray, L. J., Skinner, T., Carey, M. E., Realf, K., Dallosso, H., . . . Davies, M. J. (2012). Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care. *Bmj, 344*, e2333.

Kim, K. B., Kim, M. T., Lee, H. B., Nguyen, T., Bone, L. R., & Levine, D. (2016). Community Health Workers Versus Nurses as Counselors or Case Managers in a Self-Help Diabetes Management Program. *American Journal of Public Health, 106*(6), 1052-1058.

King, P., Peacock, I., & Donnelly, R. (1999). The UK Prospective Diabetes Study (UKPDS): clinical and therapeutic implications for type 2 diabetes. *British Journal of Clinical Pharmacology, 48*(5), 643-648. doi:10.1046/j.1365-2125.1999.00092.x

Klassen, A. C., Creswell, J., Plano Clark, V. L., Smith, K. C., & Meissner, H. I. (2012). Best practices in mixed methods for quality of life research. *Quality of Life Research, 21*(3), 377-380.

Koch, T., & Harrington, A. (1998). Reconceptualizing rigour: the case for reflexivity. *Journal of advanced nursing, 28*(4), 882-890.

Kolt, G. S., Oliver, M., Schofield, G. M., Kerse, N., Garrett, N., & Latham, N. K. (2006). An overview and process evaluation of TeleWalk: a telephone-based counseling intervention to encourage walking in older adults. *Health promotion international, 21*(3), 201-208.

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The Phq‐9. *Journal of general internal medicine, 16*(9), 606-613.

Krupnick, J. L., Sotsky, S. M., Simmens, S., Moyer, J., Elkin, I., Watkins, J., & Pilkonis, P. A. (1996). The role of the therapeutic alliance in psychotherapy and pharmacotherapy outcome: findings in the National Institute of Mental Health Treatment of Depression Collaborative Research Program. *Journal of consulting and clinical psychology, 64*(3), 532.

Lai, D., Cahill, K., Qin, Y., & Tang, J. L. (2010). Motivational interviewing for smoking cessation. *Cochrane Database Syst Rev, 1*.

Lamers, F., Jonkers Cc Fau - Bosma, H., Bosma H Fau - Knottnerus, J. A., Knottnerus Ja Fau - van Eijk, J. T. M., & van Eijk, J. T. Treating depression in diabetes patients: does a nurse-administered minimal psychological intervention affect diabetes-specific quality of life and glycaemic control? A randomized controlled trial. (1365-2648 (Electronic)).

Lane, C. (2002). The Behavior Change Counseling Index (BECCI)-Manual for Coding Behavior Change Counseling. *Retrieved May, 21*, 2003.

Lane, C., Huws-Thomas, M., Hood, K., Rollnick, S., Edwards, K., & Robling, M. (2005). Measuring adaptations of motivational interviewing: the development and validation of the behavior change counseling index (BECCI). *Patient Education and Counseling, 56*(2), 166-173. doi:http://dx.doi.org/10.1016/j.pec.2004.01.003

Lane, J. D., McCaskill, C. C., Ross, S. L., Feinglos, M. N., & Surwit, R. S. (1993). Relaxation training for NIDDM: predicting who may benefit. *Diabetes Care, 16*(8), 1087-1094.

Lane, K. L., Bocian, K. M., MacMillan, D. L., & Gresham, F. M. (2004). Treatment integrity: An essential—but often forgotten—component of school-based interventions. *Preventing School Failure: Alternative Education for Children and Youth, 48*(3), 36-43.

Lang, P. (1970). Stimulus control, response control, and the desensitization of fear. *Learning approaches to therapeutic behavior change. Chicago: Aldine*.

Laube, H. (2002). Acarbose. *Clinical drug investigation, 22*(3), 141-156.

Lean, M. E., Leslie, W. S., Barnes, A. C., Brosnahan, N., Thom, G., McCombie, L., . . . Hollingsworth, K. G. (2017). Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial. *The Lancet*.

Lee, R., Wong, T. Y., & Sabanayagam, C. (2015). Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss. *Eye and vision, 2*(1), 17.

Leech, N. L., & Onwuegbuzie, A. J. (2009). A typology of mixed methods research designs. *Quality & quantity, 43*(2), 265-275.

Leeuw, M., Goossens, M., De Vet, H., & Vlaeyen, J. (2009). The fidelity of treatment delivery can be assessed in treatment outcome studies: a successful illustration from behavioral medicine. *Journal of clinical epidemiology, 62*(1), 81-90.

Leff, H. S., & Mulkern, V. (2002). Lessons learned about science and participation from multisite evaluations. *New Directions for Evaluation, 2002*(94), 89-100.

Leventhal, H., Brissette, I., & Leventhal, E. A. (2003). The common-sense model of self-regulation of health and illness. *The self-regulation of health and illness behaviour, 1*, 42-65.

Lewin, S., Glenton, C., & Oxman, A. D. (2009). Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *Bmj, 339*, b3496.

Li, M., Li, T., Shi, B.-Y., & Gao, C.-X. (2014). Impact of motivational interviewing on the quality of life and its related factors in type 2 diabetes mellitus patients with poor long-term glycemic control. *International Journal of Nursing Sciences, 1*(3), 250-254.

Libby, P., & Theroux, P. (2005). Pathophysiology of coronary artery disease. *Circulation, 111*(25), 3481-3488.

Lin, E. H. B., Katon, W., Von Korff, M., Rutter, C., Simon, G. E., Oliver, M., . . . Young, B. (2004). Relationship of Depression and Diabetes Self-Care,

Medication Adherence, and Preventive Care. *Diabetes Care, 27*(9), 2154-2160. doi:10.2337/diacare.27.9.2154
Linnan, L. S., A. (2002). *Process Evaluation for Public Health Interventions and Research* Wiley.
Lloyd, C. E., Gill, P., & Stone, M. (2013). Psychological care in a national health service: challenges for people with diabetes. *Curr Diab Rep, 13*(6), 894-899. doi:10.1007/s11892-013-0416-6
Lobb, R., & Colditz, G. A. (2013). Implementation science and its application to population health. *Annual review of public health, 34*, 235-251.
Loveman, E., Frampton, G. K., & Clegg, A. (2008). The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review. *Health technology assessment, 12*(9), 1-136.
Luepker, R. V., Murray, D. M., Jacobs Jr, D. R., Mittelmark, M. B., Bracht, N., Carlaw, R., . . . Folsom, A. R. (1994). Community education for cardiovascular disease prevention: risk factor changes in the Minnesota Heart Health Program. *American Journal of Public Health, 84*(9), 1383-1393.
Lustman, P. J., Anderson, R. J., Freedland, K. E., De Groot, M., Carney, R. M., & Clouse, R. E. (2000). Depression and poor glycemic control: a meta-analytic review of the literature. *Diabetes Care, 23*(7), 934-942.
Lustman, P. J., Griffith, L. S., Freedland, K. E., & Clouse, R. E. (1997). The course of major depression in diabetes. *General hospital psychiatry, 19*(2), 138-143.
Lustman, P. J., Griffith, L. S., Freedland, K. E., Kissel, S. S., & Clouse, R. E. (1998). Cognitive behavior therapy for depression in type 2 diabetes mellitus: a randomized, controlled trial. *Annals of internal medicine, 129*(8), 613-621.
Lynch, E. B. L., R; Ventrelle, J; Avery, E.F; Richardson, D. (2014). A self-management intervention for African Americans with comorbid diabetes and hypertension: a pilot randomized controlled trial. . *Preventing Chronic Disease, 11*(E90).
Mackenzie, M., O'Donnell, C., Halliday, E., Sridharan, S., & Platt, S. (2010). Do health improvement programmes fit with MRC guidance on evaluating complex interventions? *British medical journal, 340*, c185.
Maddux, J. E. (2016). Self-efficacy *Interpersonal and Intrapersonal Expectancies* (pp. 55-60): Routledge.
Madson, M. B., & Campbell, T. C. (2006). Measures of fidelity in motivational enhancement: a systematic review. (0740-5472 (Print)).
Madson, M. B., Campbell, T. C., Barrett, D. E., Brondino, M. J., & Melchert, T. P. (2005). Development of the motivational interviewing supervision and training scale. *Psychology of Addictive Behaviors, 19*(3), 303.
Mainous, A. G., Tanner, R. J., Baker, R., Zayas, C. E., & Harle, C. A. (2014). Prevalence of prediabetes in England from 2003 to 2011: population-based, cross-sectional study. *BMJ open, 4*(6), e005002.
Maissi, E. (2011). Nurse led psychological interventions to improve diabetes control: assessing competencies *Patient Educ Couns, 84*, 37-43.
Malavige, L. S., & Levy, J. C. (2009). Erectile dysfunction in diabetes mellitus. *The journal of sexual medicine, 6*(5), 1232-1247.
Malpass, A., Andrews, R., & Turner, K. M. (2009). Patients with type 2 diabetes experiences of making multiple lifestyle changes: a qualitative study. *Patient Education and Counseling, 74*(2), 258-263.
Malterud, K. (2001). Qualitative research: standards, challenges, and guidelines. *The Lancet, 358*(9280), 483-488.

Mann, D. M., Ponieman, D., Leventhal, H., & Halm, E. A. (2009). Predictors of adherence to diabetes medications: the role of disease and medication beliefs. *Journal of behavioral medicine, 32*(3), 278-284.
Mannucci, E., Tesi, F., Ricca, V., Pierazzuoli, E., Barciulli, E., Moretti, S., . . . Rotella, C. M. (2002). Eating behavior in obese patients with and without type 2 diabetes mellitus. *International journal of obesity and related metabolic disorders : journal of the International Association for the Study of Obesity, 26*(6), 848-853. doi:10.1038/sj.ijo.0801976
Marchal, B., Westhorp, G., Wong, G., Van Belle, S., Greenhalgh, T., Kegels, G., & Pawson, R. (2013). Realist RCTs of complex interventions–an oxymoron. *Social Science & Medicine, 94*, 124-128.
Marín, G. (1990). *Culturally appropriate interventions in health promotion: Why and how*. Retrieved from
Markland, D., Ryan, R. M., Tobin, V. J., & Rollnick, S. (2005). Motivational interviewing and self–determination theory. *Journal of social and clinical psychology, 24*(6), 811-831.
Mars, T., Ellard, D., Carnes, D., Homer, K., Underwood, M., & Taylor, S. J. (2013). Fidelity in complex behaviour change interventions: a standardised approach to evaluate intervention integrity. *BMJ open, 3*(11), e003555.
Martino, S., Ball, S. A., Nich, C., Frankforter, T. L., & Carroll, K. M. (2008). Community program therapist adherence and competence in motivational enhancement therapy. *Drug & Alcohol Dependence, 96*(1), 37-48.
Mason, J. (2006). Mixing methods in a qualitatively driven way. *Qualitative research, 6*(1), 9-25.
McCarney, R., Warner, J., Iliffe, S., Van Haselen, R., Griffin, M., & Fisher, P. (2007). The Hawthorne Effect: a randomised, controlled trial. *BMC medical research methodology, 7*(1), 30.
McClintock, C. (1984). Toward a theory of formative program evaluation. *New Directions for Adult and Continuing Education, 1984*(24), 77-95.
McDonald, A. M., Knight, R. C., Campbell, M. K., Entwistle, V. A., Grant, A. M., Cook, J. A., . . . Roberts, I. (2006). What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials, 7*(1), 9.
McDonough, P. G. (2003). Quorum guidelines for meta-analyses. *Fertility and sterility, 80*(1), 228.
McGraw, S. A., Stone, E. J., Osganian, S. K., Elder, J. P., Perry, C. L., Johnson, C. C., . . . Luepker, R. V. (1994). Design of process evaluation within the Child and Adolescent Trial for Cardiovascular Health (CATCH). *Health education quarterly, 21*(1_suppl), S5-S26.
McKay, H. G., King, D., Eakin, E. G., Seeley, J. R., & Glasgow, R. E. (2001). The diabetes network internet-based physical activity intervention. *Diabetes Care, 24*(8), 1328-1334.
Meca, J., Rodriguez, J., & Alcazar, A. (1998). Meta-analysis de las intervenciones conductuales en el tratamiento de la diabetes en Espana. *Rev Psicol Gral Aplic, 51*, 501-516.
Mehra, B. (2002). Bias in qualitative research: Voices from an online classroom. *The Qualitative Report, 7*(1), 1-19.
Melander, A., Bitzén, P.-O., Faber, O., & Groop, L. (1989). Sulphonylurea antidiabetic drugs. *Drugs, 37*(1), 58-72.

Melkus, G. D. E., Chyun, D., Vorderstrasse, A., Newlin, K., Jefferson, V., & Langerman, S. (2010). The effect of a diabetes education, coping skills training, and care intervention on physiological and psychosocial outcomes in black women with type 2 diabetes. *Biological research for nursing, 12*(1), 7-19.

Mendenhall, E., De Silva, M. J., Hanlon, C., Petersen, I., Shidhaye, R., Jordans, M., . . . Patel, V. (2014). Acceptability and feasibility of using non-specialist health workers to deliver mental health care: stakeholder perceptions from the PRIME district sites in Ethiopia, India, Nepal, South Africa, and Uganda. *Social Science & Medicine, 118*, 33-42.

Meneghini, L. F., Spadola, J., & Florez, H. (2006). Prevalence and Associations of Binge Eating Disorder in a Multiethnic Population With Type 2 Diabetes. *Diabetes Care, 29*(12), 2760-2760. doi:10.2337/dc06-1364

Michie, S. (2016). Developing methodology for designing and evaluating theory-based complex interventions: an ontology for linking behaviour change techniques to theory, 2016.

Michie, S., Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W., . . . Wood, C. E. (2013). The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of Behavioral Medicine, 46*(1), 81-95.

Miller, W. (2000). Motivational interviewing skill code (MISC): Coder's manual. *University of New Mexico*.

Miller, W. R., & Mount, K. A. (2001). A small study of training in motivational interviewing: Does one workshop change clinician and client behavior? *Behavioural and Cognitive Psychotherapy, 29*(04), 457-471.

Miller, W. R., & Rollnick, S. (2002). Motivational interviewing: preparing people for change. 2002. *New York: Guilford Press Google Scholar*.

Miller, W. R., & Rose, G. S. (2009). Toward a theory of motivational interviewing. *American Psychologist, 64*(6), 527.

Misra, A., Wasir, J. S., & Vikram, N. K. (2005). Waist circumference criteria for the diagnosis of abdominal obesity are not applicable uniformly to all populations and ethnic groups. *Nutrition, 21*(9), 969-976.

Moffatt, S., White, M., Mackintosh, J., & Howel, D. (2006). Using quantitative and qualitative data in health services research–what happens when mixed method findings conflict?[ISRCTN61522618]. *BMC Health Services Research, 6*(1), 28.

Mohamed, H., Al-Lenjawi, B., Amuna, P., Zotor, F., & Elmahdi, H. (2013). Culturally sensitive patient-centred educational programme for self-management of type 2 diabetes: a randomized controlled trial. *Primary care diabetes, 7*(3), 199-206.

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & Group, P. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med, 6*(7), e1000097.

Mollema, E. D., Snoek, F. J., Pouwer, F., Heine, R. J., & van der Ploeg, H. M. (2000). Diabetes Fear of Injecting and Self-Testing Questionnaire: a psychometric evaluation. *Diabetes Care, 23*(6), 765-769.

Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical psychology review, 11*(3), 247-266.

Montgomery, A. A., Peters, T. J., & Little, P. (2003). Design, analysis and presentation of factorial randomised controlled trials. *BMC medical research methodology, 3*(1), 26.

Moore G, A. S., Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D, Baird J. (2014). *Process evaluation of complex interventions: Medical Research Council guidance.* Retrieved from

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., . . . Wight, D. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *Bmj, 350*, h1258.

Moriyama, M., Nakano, M., Kuroe, Y., Nin, K., Niitani, M., & Nakaya, T. (2009). Efficacy of a self‐management education program for people with type 2 diabetes: results of a 12 month trial. *Japan Journal of Nursing Science, 6*(1), 51-63.

Mowbray, C. T., Holter, M. C., Teague, G. B., & Bybee, D. (2003). Fidelity criteria: Development, measurement, and validation. *American journal of evaluation, 24*(3), 315-340.

Moyers, T., Martin, T., Catley, D., Harris, K. J., & Ahluwalia, J. S. (2003). Assessing the integrity of motivational interviewing interventions: Reliability of the motivational interviewing skills code. *Behavioural and Cognitive Psychotherapy, 31*(02), 177-184.

Moyers, T., Martin, T., Manuel, W., & Ernst, D. (2007). The Motivational Interviewing Treatment Integrity 3.0 (MITI 3.0): University of New Mexico, Center on Alcoholism, Substance Abuse, and Addictions.

Moyers, T. B., Manuel, J. K., Wilson, P. G., Hendrickson, S. M. L., Talcott, W., & Durand, P. (2008). A Randomized Trial Investigating Training in Motivational Interviewing for Behavioral Health Providers. *Behavioural and Cognitive Psychotherapy, 36*(2), 149-162. doi:10.1017/S1352465807004055

Moyers, T. B., Martin T Fau - Manuel, J. K., Manuel Jk Fau - Hendrickson, S. M. L., Hendrickson Sm Fau - Miller, W. R., & Miller, W. R. (2005a). Assessing competence in the use of motivational interviewing. (0740-5472 (Print)).

Moyers, T. B., Martin, T., Manuel, J. K., Hendrickson, S. M. L., & Miller, W. R. Assessing competence in the use of motivational interviewing. *Journal of Substance Abuse Treatment, 28*(1), 19-26. doi:10.1016/j.jsat.2004.11.001

Moyers, T. B., & Miller, W. R. (2013). Is low therapist empathy toxic? *Psychology of Addictive Behaviors, 27*(3), 878.

Moyers, T. B., Miller, W. R., & Hendrickson, S. M. (2005b). How does motivational interviewing work? Therapist interpersonal skill predicts client involvement within motivational interviewing sessions. *Journal of consulting and clinical psychology, 73*(4), 590.

MRC, A. (2000). framework for the development and evaluation of RCT's for complex interventions to improve health. 2000. *Medical Research Council: London*.

Murphy, M. E., Byrne, M., Galvin, R., Boland, F., Fahey, T., & Smith, S. M. (2017). Improving risk factor management for patients with poorly controlled type 2 diabetes: a systematic review of healthcare interventions in primary care and community settings. *BMJ open, 7*(8), e015135.

Murta, S. G., Sanderson, K., & Oldenburg, B. (2007). Process evaluation in occupational stress management programs: a systematic review. *American Journal of Health Promotion, 21*(4), 248-254.

Nadin, S., & Cassell, C. (2006). The use of a research diary as a tool for reflexive practice: Some reflections from management research. *Qualitative Research in Accounting & Management, 3*(3), 208-217.

Naji, S. A., Gibb, J., Hamilton, R. J., Lawton, K., Palin, A. N., & Eagles, J. M. (2004). How ready are practice nurses to participate in the identification and management of depressed patients in primary care? *Primary Care Mental Health, 2*(1), 47-54.

Nakahara, R., Yoshiuchi, K., Kumano, H., Hara, Y., Suematsu, H., & Kuboki, T. (2006). Prospective study on influence of psychosocial factors on glycemic control in Japanese patients with type 2 diabetes. *Psychosomatics, 47*(3), 240-246.

Nakar, S., Yitzhaki, G., Rosenberg, R., & Vinker, S. (2007). Transition to insulin in Type 2 diabetes: family physicians' misconception of patients' fears contributes to existing barriers. *Journal of Diabetes and its Complications, 21*(4), 220-226. doi:http://dx.doi.org/10.1016/j.jdiacomp.2006.02.004

Nakkash, R. T., Alaouie, H., Haddad, P., El Hajj, T., Salem, H., Mahfoud, Z., & Afifi, R. A. (2012). Process evaluation of a community-based mental health promotion intervention for refugee children. *Health Education Research, 27*(4), 595-607.

Neiger, B. L., Thackeray, R., Van Wagenen, S. A., Hanson, C. L., West, J. H., Barnes, M. D., & Fagen, M. C. (2012). Use of social media in health promotion: purposes, key performance indicators, and evaluation metrics. *Health Promotion Practice, 13*(2), 159-164.

Newman, I., Benz, C. R., & Ridenour, C. S. (1998). *Qualitative-quantitative research methodology: Exploring the interactive continuum*: SIU Press.

Newman, I., Ridenour, C., Newman, C., & De Marco, G. (2002). A typology of research purposes and its relationship to mixed methods in social and behavioral research (pp. 167-188). *Thousand Oaks, CA, EE. UU.: Sage*.

Nguyen, P., Gold, J., Pedrana, A., Chang, S., Howard, S., Ilic, O., . . . Stoove, M. (2013). Sexual health promotion on social networking sites: a process evaluation of The FaceSpace Project. *Journal of Adolescent Health, 53*(1), 98-104.

NHS Employers, U. (2004). *Investing in General Practice, The New General Medical Services Contract 2003*. Retrieved from London: https://www.nhsemployers.org/-/media/Employers/Documents/Primary-care-contracts/GMS/Archived-GMS-contract-Changes-2004-2010/2003-2004/Investing-in-General-Practice---The-New-General-Medical-Services-Contract.pdf?la=en&hash=7F830D4747ECD5221C27D990C08BE060299A6DFB

NHS England, N. (2018). NHS Diabetes Prevention Programme – digital stream . *Digital Innovations in Diabetes* Retrieved from https://www.england.nhs.uk/diabetes/digital-innovations-to-support-diabetes-outcomes/nhs-diabetes-prevention-programme-digital-stream/

NICE. (2011). Diabetes in Adults (QS6). Retrieved from http://guidance. nice.org.uk/QS6

NICE. (2014). Behaviour Change: individual approaches Retrieved from https://www.nice.org.uk/guidance/ph49

NICE. (2015). Type 2 diabetes in adults: management. *NICe Guidelines* Retrieved from https://www.nice.org.uk/guidance/ng28

Nicholson, T., Taylor, J. P., Gosden, C., Trigwell, P., & Ismail, K. (2009). National guidelines for psychological care in diabetes: how mindful have we been? *Diabetic Medicine, 26*(4), 447-450.
Nickerson, R. S. (1998). Confirmation bias: A ubiquitous phenomenon in many guises. *Review of general psychology, 2*(2), 175-220.
Nielsen, L. L. (2005). Incretin mimetics and DPP-IV inhibitors for the treatment of type 2 diabetes. *Drug discovery today, 10*(10), 703-710.
NIHR. (2002). Management of type 2 diabetes: management of blood glucose. Retrieved from
NIHR. (2017). Programme Development Grants *Funding and Support.* Retrieved from https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/programme-grants-for-applied-research/programme-development-grants.htm
Nolan, P., Murray, E., & Dallender, J. (1999). Practice nurses' perceptions of services for clients with psychological problems in primary care. *International Journal of Nursing Studies, 36*(2), 97-104.
Norris, S. L., Engelgau, M. M., & Narayan, K. V. (2001). Effectiveness of self-management training in type 2 diabetes. *Diabetes Care, 24*(3), 561-587.
Nutbeam, D. (1998). Evaluating Health Promotion—Progress, Problems and solutions. *Health promotion international, 13*(1), 27-44. doi:10.1093/heapro/13.1.27
O'Cathain, A., Murphy, E., & Nicholl, J. (2007). Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. *BMC Health Services Research, 7*(1), 85. doi:10.1186/1472-6963-7-85
O'Connor, P. J., Crabtree, B., & Yanoshik, M. K. (1997). Differences between diabetic patients who do and do not respond to a diabetes care intervention: a qualitative analysis. *Family medicine, 29*(6), 424-428.
Oakley, A., Strange, V., Bonell, C., Allen, E., & Stephenson, J. (2006). Process evaluation in randomised controlled trials of complex interventions. *BMJ (Clinical research ed.), 332*(7538), 413-416.
Ockleford, E., Shaw, R. L., Willars, J., & Dixon-Woods, M. (2008). Education and self-management for people newly diagnosed with type 2 diabetes: a qualitative study of patients' views. *Chronic Illness, 4*(1), 28-37.
Olsen, S., Smith, S. S., Oei, T. P., & Douglas, J. (2012). Motivational interviewing (MINT) improves continuous positive airway pressure (CPAP) acceptance and adherence: a randomized controlled trial. *Journal of consulting and clinical psychology, 80*(1), 151.
Onwuegbuzie, A. J. (2003). Effect sizes in qualitative research: A prolegomenon. *Quality and Quantity, 37*(4), 393-409.
Onwuegbuzie, A. J., & Leech, N. L. (2005). On becoming a pragmatic researcher: The importance of combining quantitative and qualitative research methodologies. *International journal of social research methodology, 8*(5), 375-387.
Osborn, C. Y., Amico, K. R., Cruz, N., O'Connell, A. A., Perez-Escamilla, R., Kalichman, S. C., . . . Fisher, J. D. (2010). A brief culturally tailored intervention for Puerto Ricans with type 2 diabetes. *Health Education & Behavior, 37*(6), 849-862.
Osterberg, L., & Blaschke, T. (2005). Adherence to medication. *New England Journal of Medicine, 353*(5), 487-497.

Ouriel, K. (2001). Peripheral arterial disease. *The Lancet, 358*(9289), 1257-1264.
Owens, D. R. (1998). Repaglinide–prandial glucose regulator: a new class of oral antidiabetic drugs. *Diabetic Medicine, 15*(S4 4), S28-S36.
Padmanathan, P., & De Silva, M. J. (2013). The acceptability and feasibility of task-sharing for mental healthcare in low and middle income countries: a systematic review. *Social Science & Medicine, 97*, 82-86.
Paivio, S. C., Holowaty, K. A., & Hall, I. E. (2004). The Influence of Therapist Adherence and Competence on Client Reprocessing of Child Abuse Memories. *Psychotherapy: Theory, Research, Practice, Training, 41*(1), 56.
Papachristou Nadal, I., Cliffton, C., Chamley, M., Winkley, K., Gaughran, F., & Ismail, K. (2020). Exploring healthcare professionals' perspectives of barriers and facilitators to supporting people with severe mental illness and Type 2 diabetes mellitus. *Health & social care in the community, 28*(2), 690-697.
Parsons, J. T., Rosof, E., Punzalan, J. C., & Maria, L. D. (2005). Integration of motivational interviewing and cognitive behavioral therapy to improve HIV medication adherence and reduce substance use among HIV-positive men and women: results of a pilot project. *AIDS Patient Care & STDs, 19*(1), 31-39.
Paterson, C. (2004). 'Take small steps to go a long way'consumer involvement in research into complementary and alternative therapies. *Complementary Therapies in Nursing and Midwifery, 10*(3), 150-161.
Paudel, N. R. (2009). A critical account of policy implementation theories: status and reconsideration. *Nepalese Journal of Public Policy and Governance, 25*(2), 36-54.
Pawson, R. (2013). *The science of evaluation: a realist manifesto*: sage.
Pawson, R., Greenhalgh, T., Harvey, G., & Walshe, K. (2005). Realist review–a new method of systematic review designed for complex policy interventions. *Journal of health services research & policy, 10*(suppl 1), 21-34.
Pawson, R., Tilley, N., & Tilley, N. (1997). *Realistic evaluation*: sage.
Peel, E., Douglas, M., & Lawton, J. (2007). Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. *Bmj, 335*(7618), 493.
Penckofer, S. M., Ferrans, C., Mumby, P., Byrn, M., Emanuele, M. A., Harrison, P. R., . . . Lustman, P. (2012). A psychoeducational intervention (SWEEP) for depressed women with diabetes. *Annals of Behavioral Medicine, 44*(2), 192-206.
Perry, C. L., Kelder, S. H., Murray, D. M., & Klepp, K.-I. (1992). Communitywide smoking prevention: long-term outcomes of the Minnesota Heart Health Program and the Class of 1989 Study. *American Journal of Public Health, 82*(9), 1210-1216.
Perry, C. L., Sellers, D. E., Johnson, C., Pedersen, S., Bachman, K. J., Parcel, G. S., . . . Nader, P. R. (1997). The Child and Adolescent Trial for Cardiovascular Health (CATCH): intervention, implementation, and feasibility for elementary schools in the United States. *Health Education & Behavior, 24*(6), 716-735.
Perry, C. L., Stone, E. J., Parcel, G. S., Ellison, R. C., Nader, P. R., Webber, L. S., & Luepker, R. V. (1990). School‐based cardiovascular health promotion: The child and adolescent trial for cardiovascular health (CATCH). *Journal of School Health, 60*(8), 406-413.
Peters, D., El Saharty, S., Siadat, B., Janovsky, K., & Vujicic, M. Improving Health Services in Developing Countries: From Evidence to Action. 2009. *World Bank: Washington DC*.

Peters, D. H., Adam, T., Alonge, O., Agyepong, I. A., & Tran, N. (2013). Implementation research: what it is and how to do it. *Bmj, 347*, f6753.
Peters, S., Wearden, A., Morriss, R., Dowrick, C. F., Lovell, K., Brooks, J., . . . Chew-Graham, C. (2011). Challenges of nurse delivery of psychological interventions for long-term conditions in primary care: a qualitative exploration of the case of chronic fatigue syndrome/myalgic encephalitis. *Implementation Science, 6*(1), 132.
Petersilia, J. (1990). Conditions that permit intensive supervision programs to survive. *Crime & Delinquency, 36*(1), 126-145.
Petrak, F., Stridde, E., Leverkus, F., Crispin, A. A., Forst, T., & Pfützner, A. (2007). Development and validation of a new measure to evaluate psychological resistance to insulin treatment. *Diabetes Care, 30*(9), 2199-2204.
Petrie, K. J., & Weinman, J. (1997). *Perceptions of health and illness: current research and applications*: Taylor & Francis.
Peyrot, M., Rubin Rr Fau - Lauritzen, T., Lauritzen T Fau - Snoek, F. J., Snoek Fj Fau - Matthews, D. R., Matthews Dr Fau - Skovlund, S. E., & Skovlund, S. E. (2005a). Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. (0742-3071 (Print)).
Peyrot, M., Rubin, R. R., Lauritzen, T., Snoek, F. J., Matthews, D. R., & Skovlund, S. E. (2005b). Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. *Diabetic Medicine, 22*(10), 1379-1385. doi:10.1111/j.1464-5491.2005.01644.x
Pfeifer, M. A., Halter, J. B., & Porte Jr, D. (1981). Insulin secretion in diabetes mellitus. *The American journal of medicine, 70*(3), 579-588.
Pibernik-Okanovic, M., Begic, D., Ajdukovic, D., Andrijasevic, N., & Metelko, Z. (2009). Psychoeducation versus treatment as usual in diabetic patients with subthreshold depression: preliminary results of a randomized controlled trial. *Trials, 10*(1), 1.
Piette, J. D., Richardson, C., Himle, J., Duffy, S., Torres, T., Vogel, M., . . . Valenstein, M. (2011). A randomized trial of telephone counseling plus walking for depressed diabetes patients. *Medical care, 49*(7), 641.
Pirie, P. L., Stone, E. J., Assaf, A. R., Flora, J. A., & Maschewsky-Schneider, U. (1994). Program evaluation strategies for community-based health promotion programs: perspectives from the cardiovascular disease community research and demonstration studies. *Health Education Research, 9*(1), 23-36.
Pladevall, M., Divine, G., Wells, K. E., Resnicow, K., & Williams, L. K. (2015). A randomized controlled trial to provide adherence information and motivational interviewing to improve diabetes and lipid control. *The Diabetes Educator, 41*(1), 136-146.
Plotnikoff, R., Karunamuni, N., Courneya, K., Sigal, R., Johnson, J., & Johnson, S. (2013). The Alberta Diabetes and Physical Activity Trial (ADAPT): a randomized trial evaluating theory-based interventions to increase physical activity in adults with type 2 diabetes. *Annals of Behavioral Medicine, 45*(1), 45-56.
Polonsky, W. H., Fisher, L., Earles, J., Dudl, R. J., Lees, J., Mullan, J., & Jackson, R. A. (2005). Assessing psychosocial distress in diabetes development of the diabetes distress scale. *Diabetes Care, 28*(3), 626-631.

Pourisharif, H., Babapour, J., Zamani, R., Besharat, M. A., Mehryar, A. H., & Rajab, A. (2010). The effectiveness of motivational interviewing in improving health outcomes in adults with type 2 diabetes. *Procedia-Social and Behavioral Sciences, 5*, 1580-1584.

Pratley, R. E. (2013). The early treatment of type 2 diabetes. *The American journal of medicine, 126*(9), S2-S9.

Price, R. H., Friedland, D. S., Choi, J. N., & Caplan, R. D. (1998). Job-loss and work transitions in a time of global economic change.

Prochaska, J. O., & DiClemente, C. C. (1982). Transtheoretical therapy: Toward a more integrative model of change. *Psychotherapy: theory, research & practice, 19*(3), 276.

Prochaska, J. O., DiClemente, C. C., Velicer, W. F., Ginpil, S., & Norcross, J. C. (1985). Predicting change in smoking status for self-changers. *Addictive behaviors, 10*(4), 395-406.

Prytys, M., Garety, P., Jolley, S., Onwumere, J., & Craig, T. (2011). Implementing the NICE guideline for schizophrenia recommendations for psychological therapies: a qualitative analysis of the attitudes of CMHT staff. *Clinical psychology & psychotherapy, 18*(1), 48-59.

QSR. (2016). NVivo 11.

Rabkin, S. W., Boyko, E., Wilson, A., & Streja, D. A. (1983). A randomized clinical trial comparing behavior modification and individual counseling in the nutritional therapy of non-insulin-dependent diabetes mellitus: comparison of the effect on blood sugar, body weight, and serum lipids. *Diabetes Care, 6*(1), 50-56.

Reddy, J., Wilhelm, K., & Campbell, L. (2013). Putting PAID to diabetes-related distress: the potential utility of the problem areas in diabetes (PAID) scale in patients with diabetes. *Psychosomatics, 54*(1), 44-51.

Reiser, R. A. (2001). A history of instructional design and technology: Part II: A history of instructional design. *Educational technology research and development, 49*(2), 57-67.

Reitan, R. M. (1992). *Trail Making Test: Manual for administration and scoring*: Reitan Neuropsychology Laboratory.

Resnicow, K., Davis, M., Smith, M., Lazarus-Yaroch, A., Baranowski, T., Baranowski, J., . . . Wang, D. T. (1998). How best to measure implementation of school health curricula: a comparison of three measures. *Health Education Research, 13*(2), 239-250.

Reynolds, K. D., Franklin, F. A., Leviton, L. C., Maloy, J., Harrington, K. F., Yaroch, A. L., . . . Jester, P. (2000). Methods, results, and lessons learned from process evaluation of the high 5 school-based nutrition intervention. *Health Education & Behavior, 27*(2), 177-186.

Rhodes, P., Nocon, A., Booth, M., Chowdrey, M., Fabian, A., Lambert, N., . . . Walgrove, T. (2002). A service users' research advisory group from the perspectives of both service users and researchers. *Health & social care in the community, 10*(5), 402-409.

Ridgeway, N. A., Harvill, D. R., Harvill, L. M., Falin, T. M., Forester, G. M., & Gose, O. D. (1999). Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *Southern medical journal, 92*(7), 667-672.

Ritchie, J. L., J. (2011). *Qualitative Research Practice: a guide for social science students and researchers*: Sage

Robbins, S. C. C., Ward, K., & Skinner, S. R. (2011). School-based vaccination: a systematic review of process evaluations. *Vaccine, 29*(52), 9588-9599.
Roberts, S. (2007). *Working Together For Better Diabetes Care: Clinical Case for Change* Retrieved from http://webarchive.nationalarchives.gov.uk/20080814090248/dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074702
Robinson, T. E. (2003). Addiction *Annual Review of Psychology, 54*, 25-53.
Rogers, C. R. (1951). *Client-centered therapy: Its current practice, implications, and theory, with chapters*: Houghton Mifflin.
Rojas, L. B. A., & Gomes, M. B. (2013). Metformin: an old but still the best treatment for type 2 diabetes. *Diabetology & metabolic syndrome, 5*(1), 6.
Roland, M. S., B; McDonald, R (2007). Care Closer to Home: Moving Care *Health Service Journal, 117*, 6-8.
Rollnick, S., & Miller, W. R. (1995). What is motivational interviewing? *Behavioural and Cognitive Psychotherapy, 23*(04), 325-334.
Romano, M., & Peters, L. (2016). Understanding the process of motivational interviewing: A review of the relational and technical hypotheses. *Psychotherapy Research, 26*(2), 220-240.
Rothschild, S. K., Martin, M. A., Swider, S. M., Tumialán Lynas, C. M., Janssen, I., Avery, E. F., & Powell, L. H. (2014). Mexican American trial of community health workers: a randomized controlled trial of a community health worker intervention for Mexican Americans with type 2 diabetes mellitus. *American Journal of Public Health, 104*(8), 1540-1548.
Rothwell, P. M. (2005). External validity of randomised controlled trials:"to whom do the results of this trial apply?". *The Lancet, 365*(9453), 82-93.
Sacco, W. P., Malone, J. I., Morrison, A. D., Friedman, A., & Wells, K. (2009). Effect of a brief, regular telephone intervention by paraprofessionals for type 2 diabetes. *Journal of behavioral medicine, 32*(4), 349-359.
Safren, S. A., Gonzalez, J. S., Wexler, D. J., Psaros, C., Delahanty, L. M., Blashill, A. J., . . . Cagliero, E. (2013). A randomized controlled trial of cognitive behavioral therapy for adherence and depression (CBT-AD) in patients with uncontrolled type 2 diabetes. *Diabetes Care*, DC_130816.
Sale, J. E. M., Lohfeld, L. H., & Brazil, K. (2002). Revisiting the Quantitative-Qualitative Debate: Implications for Mixed-Methods Research. *Quality and Quantity, 36*(1), 43-53. doi:10.1023/a:1014301607592
Sánchez, V., Steckler, A., Nitirat, P., Hallfors, D., Cho, H., & Brodish, P. (2007). Fidelity of implementation in a treatment effectiveness trial of reconnecting youth. *Health Education Research, 22*(1), 95-107.
Sanders, C., Rogers, A., Bowen, R., Bower, P., Hirani, S., Cartwright, M., . . . Newman, S. P. (2012). Exploring barriers to participation and adoption of telehealth and telecare within the Whole System Demonstrator trial: a qualitative study. *BMC Health Services Research, 12*(1), 220. doi:10.1186/1472-6963-12-220
Sanson-Fisher, R. W., Bonevski, B., Green, L. W., & D'Este, C. (2007). Limitations of the randomized controlled trial in evaluating population-based health interventions. *American journal of preventive medicine, 33*(2), 155-161.
Santacroce, S. J., Maccarelli, L. M., & Grey, M. (2004). Intervention fidelity. *Nursing research, 53*(1), 63-66.

Saunders, R. P., Evans, M. H., & Joshi, P. (2005). Developing a Process-Evaluation Plan for Assessing Health Promotion Program Implementation: A How-To Guide. *Health Promotion Practice, 6*(2), 134-147. doi:10.1177/1524839904273387

Savelkoul, M., & de Witte, L. (2001). Development, content, and process evaluation of a coping intervention for patients with rheumatic diseases. *Patient Education and Counseling, 45*(3), 163-172.

Scanlon, J. W., Horst, P., Nay, J. N., Schmidt, R. E., & Waller, A. (1977). Evaluability assessment: Avoiding type III and IV errors. *Evaluation management: A source book of readings*, 71-90.

Schaffer, N. D. (1983). Methodological issues of measuring the skillfulness of therapeutic techniques. *Psychotherapy: theory, research & practice, 20*(4), 486.

Scheen, A. J. (2010). Dipeptidylpeptidase-4 inhibitors (gliptins). *Clinical pharmacokinetics, 49*(9), 573-588.

Schellenberg, E. S., Dryden, D. M., Vandermeer, B., Ha, C., & Korownyk, C. (2013). Lifestyle interventions for patients with and at risk for type 2 diabetes: a systematic review and meta-analysis. *Annals of internal medicine, 159*(8), 543-551.

Schmidt, M. (1996). *Rey auditory verbal learning test: a handbook*: Western Psychological Services Los Angeles.

Schmitt, A., Reimer, A., Kulzer, B., Haak, T., Gahr, A., & Hermanns, N. (2015). Negative association between depression and diabetes control only when accompanied by diabetes-specific distress. *Journal of behavioral medicine, 38*(3), 556-564.

Schneeweiss, S. (2014). Learning from big health care data. *New England Journal of Medicine, 370*(23), 2161-2163.

Schoenwald, S. K., & Hoagwood, K. (2001). Effectiveness, transportability, and dissemination of interventions: What matters when? *Psychiatric Services*.

Schoonjans, K., & Auwerx, J. (2000). Thiazolidinediones: an update. *The Lancet, 355*(9208), 1008-1010.

Schreurs, K. M., Colland, V. T., Kuijer, R. G., de Ridder, D. T., & van Elderen, T. (2003). Development, content, and process evaluation of a short self-management intervention in patients with chronic diseases requiring self-care behaviours. *Patient Education and Counseling, 51*(2), 133-141.

Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC medicine, 8*(1), 18.

Scriven, M. (1996). The theory behind practical evaluation. *Evaluation, 2*(4), 393-404.

Searle, A., Norman, P., Thompson, R., & Vedhara, K. (2007). A prospective examination of illness beliefs and coping in patients with type 2 diabetes. *British journal of health psychology, 12*(4), 621-638.

Shen, J., Yang, H., Cao, H., & Warfield, C. (2008). The fidelity—Adaptation relationship in non-evidence-based programs and its implication for program evaluation. *Evaluation, 14*(4), 467-481.

Shepperd, S., Lewin, S., Straus, S., Clarke, M., Eccles, M. P., Fitzpatrick, R., . . . Sheikh, A. (2009). Can we systematically review studies that evaluate complex interventions? *PLoS Med, 6*(8), e1000086.

Sheridan, S. M., Swanger-Gagné, M., Welch, G. W., Kwon, K., & Garbacz, S. A. (2009). Fidelity measurement in consultation: Psychometric issues and preliminary examination. *School Psychology Review, 38*(4), 476.

Shi, Q., Ostwald, S. K., & Wang, S. (2010). Improving glycaemic control self‐efficacy and glycaemic control behaviour in Chinese patients with Type 2 diabetes mellitus: randomised controlled trial. *Journal of clinical nursing, 19*(3‐4), 398-404.

Siddaway, A. P., Wood, A. M., & Hedges, L. V. (2019). How to do a systematic review: a best practice guide for conducting and reporting narrative reviews, meta-analyses, and meta-syntheses. *Annual Review of Psychology, 70*, 747-770.

Sina, M., Graffy, J., & Simmons, D. (2018). Associations between barriers to self-care and diabetes complications among patients with type 2 diabetes. *Diabetes research and clinical practice, 141*, 126-131.

Singal, A. G., Higgins, P. D., & Waljee, A. K. (2014). A primer on effectiveness and efficacy trials. *Clinical and translational gastroenterology, 5*(1), e45.

Skivington, K., Matthews, L., Craig, P., Simpson, S., & Moore, L. (2018). Developing and evaluating complex interventions: updating Medical Research Council guidance to take account of new methodological and theoretical approaches. *The Lancet, 392*, S2.

Smith, D. E., Heckemeyer, C. M., Kratt, P. P., & Mason, D. A. (1997). Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM: a pilot study. *Diabetes Care, 20*(1), 52-54.

Snoek, F., & Skinner, T. (2002). Psychological counselling in problematic diabetes: does it help? *Diabetic Medicine, 19*(4), 265-273.

Snoek, F. J., Bremmer, M. A., & Hermanns, N. (2015). Constructs of depression and distress in diabetes: time for an appraisal. *The Lancet Diabetes & Endocrinology, 3*(6), 450-460.

Snoek, F. J., Kersch Ny Fau - Eldrup, E., Eldrup E Fau - Harman-Boehm, I., Harman-Boehm I Fau - Hermanns, N., Hermanns N Fau - Kokoszka, A., Kokoszka A Fau - Matthews, D. R., . . . Skovlund, S. E. (2011). Monitoring of Individual Needs in Diabetes (MIND): baseline data from the Cross-National Diabetes Attitudes, Wishes, and Needs (DAWN) MIND study. (1935-5548 (Electronic)). doi:D - NLM: PMC3041189 EDAT- 2011/01/27 06:00 MHDA- 2011/06/09 06:00 CRDT- 2011/01/27 06:00 PHST- 2011/01/25 [aheadofprint] AID - dc10-1552 [pii] AID - 10.2337/dc10-1552 [doi] PST - ppublish

Snowdon, C. (2015). Qualitative and mixed methods research in trials. *Trials, 16*(1), 1.

Sofaer, S. (2002). Qualitative research methods. *International journal for quality in health care, 14*(4), 329-336.

Sorensen, G., Thompson, B., Glanz, K., Feng, Z., Kinne, S., DiClemente, C., . . . Lichtenstein, E. (1996). Work site-based cancer prevention: primary results from the Working Well Trial. *American Journal of Public Health, 86*(7), 939-947.

Spanou, C., Simpson, S. A., Hood, K., Edwards, A., Cohen, D., Rollnick, S., . . . Randell, E. (2010). Preventing disease through opportunistic, r apid e ngag em ent by p rimary c are t eams using b ehaviour c hange c ounselling (PRE-EMPT): protocol for a general practice-based cluster randomised trial. *BMC family practice, 11*(1), 1.

Speller, V., Learmonth, A., & Harrison, D. (1997). The search for evidence of effective health promotion. *BMJ: British Medical Journal, 315*(7104), 361.
Speller, V., Wimbush, E., & Morgan, A. (2005). Evidence-based health promotion practice: how to make it work. *Global Health Promotion*, 15.
Spiegel, A. (2011). Creator Of Psychopathy Test Worries About Its Use. *All Things Considered* Retrieved from https://www.npr.org/2011/05/27/136723357/creator-of-psychopathy-test-worries-about-its-use
Spijker, A., Teerenstra, S., Wollersheim, H., Adang, E., Verhey, F., & Vernooij-Dassen, M. (2013). Influence of adherence to a systematic care program for caregivers of dementia patients. *The American Journal of Geriatric Psychiatry, 21*(1), 26-36.
Steinmetz, H., Knappstein, M., Ajzen, I., Schmidt, P., & Kabst, R. (2016). How Effective are Behavior Change Interventions Based on the Theory of Planned Behavior? *Zeitschrift für Psychologie*.
Stigler, S. M. (1992). A historical view of statistical concepts in psychology and educational research. *American Journal of Education, 101*(1), 60-70.
Stoop, C., Nefs, G., Pop, V., Wijnands‐van Gent, C., Tack, C., Geelhoed‐Duijvestijn, P., . . . Pouwer, F. (2014). Diabetes‐specific emotional distress in people with Type 2 diabetes: a comparison between primary and secondary care. *Diabetic Medicine, 31*(10), 1252-1259.
Story, M., Mays, R. W., Bishop, D. B., Perry, C. L., Taylor, G., Smyth, M., & Gray, C. (2000). 5-a-day Power Plus: process evaluation of a multicomponent elementary school program to increase fruit and vegetable consumption. *Health Education & Behavior, 27*(2), 187-200.
Strandberg, R. B., Graue, M., Wentzel-Larsen, T., Peyrot, M., & Rokne, B. (2014). Relationships of diabetes-specific emotional distress, depression, anxiety, and overall well-being with HbA1c in adult persons with type 1 diabetes. *Journal of psychosomatic research, 77*(3), 174-179.
Street, R. L., & Haidet, P. (2011). How well do doctors know their patients? Factors affecting physician understanding of patients' health beliefs. *Journal of general internal medicine, 26*(1), 21-27.
Strupp, H. H. (1986). Psychotherapy: Research, practice, and public policy: How to avoid dead ends. *American Psychologist, 41*(2), 120.
Stuckey, H. L., Dellasega, C., Graber, N. J., Mauger, D. T., Lendel, I., & Gabbay, R. A. (2009). Diabetes nurse case management and motivational interviewing for change (DYNAMIC): study design and baseline characteristics in the Chronic Care Model for type 2 diabetes. *Contemporary clinical trials, 30*(4), 366-374.
Sturt, J. A., Whitlock, S., Fox, C., Hearnshaw, H., Farmer, A., Wakelin, M., . . . Dale, J. (2008). Effects of the Diabetes Manual 1: 1 structured education in primary care. *Diabetic Medicine, 25*(6), 722-731.
Suchman, E. (1968). *Evaluative Research: Principles and Practice in Public Service and Social Action Progr*: Russell Sage Foundation.
Sully, B. G., Julious, S. A., & Nicholl, J. (2013). A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. *Trials, 14*(1), 166.
Surwit, R. S., Van Tilburg, M. A., Zucker, N., McCaskill, C. C., Parekh, P., Feinglos, M. N., . . . Lane, J. D. (2002). Stress management improves long-term glycemic control in type 2 diabetes. *Diabetes Care, 25*(1), 30-34.

Sutton, S. (2001). Back to the drawing board? A review of applications of the transtheoretical model to substance use. *Addiction, 96*(1), 175-186.
Szulanski, G., & Winter, S. (2002). Getting it right the second time. *Harvard business review, 80*(1), 62-69, 125.
Tak‐Ying Shiu, A., Kwan, J. J. Y. M., & Wong, R. Y. M. (2003). Social stigma as a barrier to diabetes self‐management: implications for multi‐level interventions. *Journal of clinical nursing, 12*(1), 149-150.
Tan, A., Muthusamy, L., Ng, C., Phoon, K., Ow, J., & Tan, N. (2011). Initiation of insulin for type 2 diabetes mellitus patients: what are the issues? A qualitative study. *Singapore medical journal, 52*(11), 801.
Taylor, M. J., McNicholas, C., Nicolay, C., Darzi, A., Bell, D., & Reed, J. E. (2014). Systematic review of the application of the plan–do–study–act method to improve quality in healthcare. *BMJ Qual Saf, 23*(4), 290-298.
Taylor, S. I., Blau, J. E., & Rother, K. I. (2015). SGLT2 inhibitors may predispose to ketoacidosis. *The Journal of Clinical Endocrinology & Metabolism, 100*(8), 2849-2852.
Teddlie, C., & Tashakkori, A. (2003). *Handbook of mixed methods in social & behavioral research*: Sage.
Teixeira, M. E., & Budd, G. M. (2010). Obesity stigma: a newly recognized barrier to comprehensive and effective type 2 diabetes management. *Journal of the American Association of Nurse Practitioners, 22*(10), 527-533.
The National Archives, U. (2012). *Health and Social Care Act 2012*. Retrieved from http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted.
Tidy, D. C. (2014). Different Levels of Evidence Retrieved from https://patient.info/doctor/different-levels-of-evidence
Trief, P. M., Izquierdo, R., Eimicke, J. P., Teresi, J. A., Goland, R., Palmas, W., . . . Weinstock, R. S. (2013). Adherence to diabetes self care for white, African-American and Hispanic American telemedicine participants: 5 year results from the IDEATel project. *Ethnicity & health, 18*(1), 83-96.
Trude, S., & Stoddard, J. J. (2003). Referral gridlock. *Journal of general internal medicine, 18*(6), 442-449.
Trude, S. S., JJ. (2003). Primary Care Physicians and Mental Health Services *Journal of General Internal Medicine, 18*, 442-449.
Tsujiuchi, T., Kumano, H., Yoshiuchi, K., He, D., Tsujiuchi, Y., Kuboki, T., . . . Hirao, K. (2002). The effect of Qi-Gong relaxation exercise on the control of type 2 diabetes mellitus. *Diabetes Care, 25*(1), 241-242.
Turrisi, R., Larimer, M. E., Mallett, K. A., Kilmer, J. R., Ray, A. E., Mastroleo, N. R., . . . Lostutter, T. W. (2009). A randomized clinical trial evaluating a combined alcohol intervention for high-risk college students. *Journal of studies on alcohol and drugs, 70*(4), 555-567.
Tyler, R. W. (1975). Educational Benchmarks in Retrospect: Educational Change Since 1915. *Viewpoints, 51*(2), 12-31.
Tyler, R. W., Gagné, R. M., & Scriven, M. (1967). *Perspectives of curriculum evaluation* (Vol. 1): Rand McNally.
UK, C. (2017). Critical Appraisal Skills Programme (CASP). Retrieved from http://www.casp-uk.net/
UK, D. (2011). Type 1 diabetes Priority Setting Partnership. Retrieved from https://www.diabetes.org.uk/research/our-approach-to-research/have-your-say/type-1-diabetes-priority-setting-partnership

UK, D. (2016). Diabetes, Facts and Stats, October 2016. Retrieved from https://www.diabetes.org.uk/Documents/Position statements/DiabetesUK_Facts_Stats_Oct16.pdf

UK Prospective Diabetes Study Group, U. (1998). Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *The Lancet, 352*(9131), 837-853.

Van Bastelaar, K. M. P., Pouwer, F., Geelhoed-Duijvestijn, P. H. L. M., Tack, C. J., Bazelmans, E., Beekman, A. T., . . . Snoek, F. J. (2010). Diabetes-specific emotional distress mediates the association between depressive symptoms and glycaemic control in Type 1 and Type 2 diabetes. *Diabetic Medicine, 27*(7), 798-803. doi:10.1111/j.1464-5491.2010.03025.x

Van Belle, S., Wong, G., Westhorp, G., Pearson, M., Emmel, N., Manzano, A., & Marchal, B. (2016). Can "realist" randomised controlled trials be genuinely realist? *Trials, 17*(1), 313.

Van de Mortel, T. F. (2008). Faking it: social desirability response bias in self-report research. *Australian Journal of Advanced Nursing, The, 25*(4), 40.

Van Lange, P. A., Kruglanski, A. W., & Higgins, E. T. (2011). *Handbook of theories of social psychology: Volume two* (Vol. 2): SAGE publications.

VanBuskirk, K. A., & Wetherell, J. L. (2014). Motivational interviewing with primary care populations: a systematic review and meta-analysis. *Journal of behavioral medicine, 37*(4), 768-780.

Vinik, A. I. (2016). Diabetic sensory and motor neuropathy. *New England Journal of Medicine, 374*(15), 1455-1464.

Vinik, A. I., Maser, R. E., Mitchell, B. D., & Freeman, R. (2003). Diabetic autonomic neuropathy. *Diabetes Care, 26*(5), 1553-1579.

Von Elm, E., Altman, D. G., Egger, M., Pocock, S. J., Gøtzsche, P. C., & Vandenbroucke, J. P. (2008). The Strengthening the Reporting of Observational Studies in Epidemiology [STROBE] statement: guidelines for reporting observational studies. *Gaceta Sanitaria, 22*(2), 144-150.

Wain, R. M., Kutner, B. A., Smith, J. L., Carpenter, K. M., Hu, M.-C., Amrhein, P. C., & Nunes, E. V. (2015). Self-report after randomly assigned supervision does not predict ability to practice Motivational Interviewing. *Journal of Substance Abuse Treatment, 57*, 96-101.

Waker, C. L. (2012). *The Effects of Motivational Interviewing on Diabetes Self-Management Behaviors and Glycemic Control in Type 2 Diabetes: A Translational Study.* University of Cincinnati.

Walker, C., Furler, J., Blackberry, I., Dunbar, J., Young, D., & Best, J. (2011). The delivery of a telephone coaching programme to people with type 2 diabetes by practice nurses in Victoria, Australia: a qualitative evaluation. *Journal of Nursing and Healthcare of Chronic Illness, 3*(4), 419-426.

Wallace, L., & Turner, F. (2009). A systematic review of psychometric evaluation of motivational interviewing integrity measures. *Journal of Teaching in the Addictions, 8*(1-2), 84-123.

Wallace, L. T., A; Kosmala-Anderson, J; Sharma, S; Jesuthasan, J; Bourne, C; Realpe, A. (2012). *Co-creating Health: Evaluation of the First Phase* Retrieved from https://books.google.co.uk/books?id=fIlbrbvXFf0C&printsec=frontcover&source=gbs_ge_summary_r&cad=0 - v=onepage&q&f=false

Wallace, T., & Matthews, D. (2000). Poor glycaemic control in type 2 diabetes: a conspiracy of disease, suboptimal therapy and attitude. *Qjm, 93*(6), 369-374.
Wanless, D. (2002). Securing our future health: taking a long-term view. *London: HM Treasury, 16*.
Ware Jr, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical care, 34*(3), 220-233.
Wearden, A., Riste, L., Dowrick, C., Chew-Graham, C., Bentall, R., Morriss, R., . . . Lovell, K. (2006). Fatigue Intervention by Nurses Evaluation–The FINE Trial. A randomised controlled trial of nurse led self-help treatment for patients in primary care with chronic fatigue syndrome: study protocol.[ISRCTN74156610]. *BMC medicine, 4*(1), 9.
Wechsler, D. (2001). *Wechsler Test of Adult Reading: WTAR*: Psychological Corporation.
Weinger, K., Butler, H. A., Welch, G. W., & La Greca, A. M. (2005). Measuring Diabetes Self-Care A psychometric analysis of the Self-Care Inventory-revised with adults. *Diabetes Care, 28*(6), 1346-1352.
Weissman, A. N., & Beck, A. T. (1978). Development and validation of the Dysfunctional Attitude Scale: A preliminary investigation.
Welch, G., Zagarins, S. E., Feinberg, R. G., & Garb, J. L. (2011). Motivational interviewing delivered by diabetes educators: does it improve blood glucose control among poorly controlled type 2 diabetes patients? *Diabetes research and clinical practice, 91*(1), 54-60.
Welschen, L. M., van Oppen, P., Bot, S. D., Kostense, P. J., Dekker, J. M., & Nijpels, G. (2013). Effects of a cognitive behavioural treatment in patients with type 2 diabetes when added to managed care; a randomised controlled trial. *Journal of behavioral medicine, 36*(6), 556-566.
Wessely, S., Slade, M., & Priebe, S. (2007). Randomised, controlled trials. *Choosing Methods in Mental Health Research: Mental Health Research from Theory to Practice*, 85.
West, D. S., DiLillo, V., Bursac, Z., Gore, S. A., & Greene, P. G. (2007). Motivational Interviewing Improves Weight Loss in Women With Type 2 Diabetes. *Diabetes Care, 30*(5), 1081-1087. doi:10.2337/dc06-1966
White, N., Carnahan, J., Nugent, C., Iwaoka, T., & Dodson, M. (1986). Management of obese patients with diabetes mellitus: comparison of advice education with group management. *Diabetes Care, 9*(5), 490-496.
Whittemore, R., Melkus, G. D., Sullivan, A., & Grey, M. (2004). A nurse-coaching intervention for women with type 2 diabetes. *Diabetes Educ, 30*(5), 795-804.
WHO. (2006). Definition and Diagnosis of Diabetes Mellitus and Intermediate Hyperglycaemia Retrieved from http://www.who.int/diabetes/publications/Definition and diagnosis of diabetes_new.pdf
WHO. (2011). Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus Retrieved from http://www.who.int/diabetes/publications/report-hba1c_2011.pdf
WHO. (2016). Global Report on Diabetes
Wierenga, D., Engbers, L. H., Van Empelen, P., Duijts, S., Hildebrandt, V. H., & Van Mechelen, W. (2013). What is actually measured in process evaluations for worksite health promotion programs: a systematic review. *BMC Public Health, 13*(1), 1.

Wikblad, K. F. (1991). Patient perspectives of diabetes care and education. *Journal of advanced nursing, 16*(7), 837-844.
Wilcox, G. (2005). Insulin and Insulin Resistance. *Clinical Biochemist Reviews, 26*(2), 19-39.
Wilfley, D. (2011). Binge Eating, Mood, and Quality of Life in Youth With Type 2 Diabetes. *Baseline data from the TODAY study, 34*(4), 858-860. doi:10.2337/dc10-1704
Williams, R., Van Gaal, L., & Lucioni, C. (2002). Assessing the impact of complications on the costs of Type II diabetes. *Diabetologia, 45*(1), S13-S17.
Windsor, R. A., Baranowski, T., Clark, N., & Cutter, G. (1984). Evaluation of health promotion and education programs.
Wing, R. R., Epstein, L. H., Nowalk, M. P., Koeske, R., & Hagg, S. (1985). Behavior change, weight loss, and physiological improvements in type II diabetic patients. *Journal of consulting and clinical psychology, 53*(1), 111.
Wing, R. R., Marcus, M. D., Epstein, L. H., & Jawad, A. (1991). A" family-based" approach to the treatment of obese type II diabetic patients. *Journal of consulting and clinical psychology, 59*(1), 156.
Winkleby, M. A., Feighery, E., Dunn, M., Kole, S., Ahn, D., & Killen, J. D. (2004). Effects of an advocacy intervention to reduce smoking among teenagers. *Archives of pediatrics & adolescent medicine, 158*(3), 269-275.
Winkley, K., Evwierhoma, C., Amiel, S., Lempp, H., Ismail, K., & Forbes, A. (2015). Patient explanations for non‐attendance at structured diabetes education sessions for newly diagnosed Type 2 diabetes: a qualitative study. *Diabetic Medicine, 32*(1), 120-128.
Winkley, K., Ismail, K., Landau, S., & Eisler, I. (2006). Psychological interventions to improve glycaemic control in patients with type 1 diabetes: systematic review and meta-analysis of randomised controlled trials. *BMJ, 333*(7558), 65. doi:10.1136/bmj.38874.652569.55
Winkley, K., Stahl, D., Chamley, M., Stopford, R., Boughdady, M., Thomas, S., . . . Ismail, K. (2016). Low attendance at structured education for people with newly diagnosed type 2 diabetes: General practice characteristics and individual patient factors predict uptake. *Patient Education and Counseling, 99*(1), 101-107.
Winter, S. C. (2012). Implementation perspectives: Status and reconsideration. *The Sage handbook of public administration*, 265-278.
Wolever, R., Dreusicke, M., Fikkan, J., Hawkins, T., Yeung, S., Wakefield, J., . . . Skinner, E. (2010). Integrative health coaching for patients with type 2 diabetes a randomized clinical trial. *The Diabetes Educator, 36*(4), 629-639.
Worthen, B. R., & Sanders, J. R. (1987). Educational evaluation: Alternative approaches and practical guidelines.
Wu, S.-F. V., Huang, Y.-C., Liang, S.-Y., Wang, T.-J., Lee, M.-C., & Tung, H.-H. (2011). Relationships among depression, anxiety, self-care behaviour and diabetes education difficulties in patients with type-2 diabetes: A cross-sectional questionnaire survey. *International Journal of Nursing Studies, 48*(11), 1376-1383. doi:http://dx.doi.org/10.1016/j.ijnurstu.2011.04.008
Wyatt, K., Carter, M., Mahtani, V., Barnard, A., Hawton, A., & Britten, N. (2008). The impact of consumer involvement in research: an evaluation of consumer involvement in the London Primary Care Studies Programme. *Family Practice, 25*(3), 154-161.

Young, H., Miyamoto, S., Ward, D., Dharmar, M., Tang-Feldman, Y., & Berglund, L. (2014). Sustained effects of a nurse coaching intervention via telehealth to improve health behavior change in diabetes. *Telemedicine and e-Health, 20*(9), 828-834.

Young, J., & Beck, A. T. (1980). Cognitive therapy scale: Rating manual. *Unpublished manuscript*, 36th.

Zimmerman, B. R. (1997). Sulfonylureas. *Endocrinology and metabolism clinics of North America, 26*(3), 511-522.

Appendices

Appendix 1: Search Strategy for Scoping Study (MEDLINE via PubMed)

(process[All Fields] AND ("evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation"[All Fields])) AND ("psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields])

((process[All Fields] AND ("evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation"[All Fields])) AND psychological[All Fields]) AND ("Intervention (Amstelveen)"[Journal] OR "Interv Sch Clin"[Journal] OR "intervention"[All Fields])

((process[All Fields] AND ("evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation"[All Fields])) AND motivational[All Fields]) AND ("interviews as topic"[MeSH Terms] OR ("interviews"[All Fields] AND "topic"[All Fields]) OR "interviews as topic"[All Fields] OR "interviewing"[All Fields])

(((process[All Fields] AND ("evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation"[All Fields])) AND cognitive[All Fields]) AND behavioural[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])

((process[All Fields] AND ("evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation"[All Fields])) AND psychological[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])

((process[All Fields] AND ("evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation"[All Fields])) AND cognitive[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])

((fidelity[All Fields] OR adherence[All Fields]) OR implementation[All Fields]) AND ("psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields])

(((fidelity[All Fields] OR adherence[All Fields]) OR implementation[All Fields]) AND psychological[All Fields]) AND ("Intervention (Amstelveen)"[Journal] OR "Interv Sch Clin"[Journal] OR "intervention"[All Fields])

(((fidelity[All Fields] OR adherence[All Fields]) OR implementation[All Fields]) AND motivational[All Fields]) AND ("interviews as topic"[MeSH Terms] OR ("interviews"[All Fields] AND "topic"[All Fields]) OR "interviews as topic"[All Fields] OR "interviewing"[All Fields])

((((fidelity[All Fields] OR adherence[All Fields]) OR implementation[All Fields]) AND cognitive[All Fields]) AND behavioural[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])

(((fidelity[All Fields] OR adherence[All Fields]) OR implementation[All Fields]) AND psychological[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])

("Intervention (Amstelveen)"[Journal] OR "Interv Sch Clin"[Journal] OR "intervention"[All Fields]) AND integrity[All Fields]

(("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND integrity[All Fields]) AND ("psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields])

((("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND integrity[All Fields]) AND psychological[All Fields]) AND ("Intervention (Amstelveen)"[Journal] OR "Interv Sch Clin"[Journal] OR "intervention"[All Fields])

((("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND integrity[All Fields]) AND motivational[All Fields]) AND ("interviews as topic"[MeSH Terms] OR ("interviews"[All Fields] AND "topic"[All Fields]) OR "interviews as topic"[All Fields] OR "interviewing"[All Fields])

((((("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND integrity[All Fields]) AND cognitive[All Fields]) AND behavioural[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])

(("Intervention (Amstelveen)"[Journal] OR "Interv Sch Clin"[Journal] OR "intervention"[All Fields]) AND integrity[All Fields]) AND ("psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields])

Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])

((((("Intervention (Amstelveen)"[Journal] OR "Interv Sch Clin"[Journal] OR "intervention"[All Fields]) AND integrity[All Fields]) AND cognitive[All

((("Intervention (Amstelveen)"[Journal] OR "Interv Sch Clin"[Journal] OR "intervention"[All Fields]) AND integrity[All Fields]) AND motivational[All Fields]) AND ("interviews as topic"[MeSH Terms] OR ("interviews"[All Fields] AND "topic"[All Fields]) OR "interviews as topic"[All Fields] OR "interviewing"[All Fields])

Appendix 1 Continued: Search Strategy for Literature Review

MEDLINE

1. exp Diabetes Mellitus/
2. diabet$.ab,ti.
3. (DKA or IDDM).mp. or DMI.ab,ti. [mp=title, original title, abstract, name of substance word, subject heading word]
4. (MODY or DM2 or NIDDM).mp. or IIDM.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
5. insulin$ secret$ dysfunc$.ti,ab.
6. insulin$ resist$.ti,ab.
7. ((impaired glucose tolerance or glucose intoleran$ or insulin$ resist$) and (DM or DM2)).ti,ab.
8. insulin$ depend$.mp. or insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
9. (non insulin$ depend$ or nonisulin$ depend$ or nonisulin?depend).mp. or non insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
10. (("typ$ 1" or typ$ I) adj6 DM).ti,ab.
11. (("typ$ 2" or typ$ II) adj6 DM).ti,ab.
12. ((juvenil$ or child$ or keto$ or labil$ or brittl$ or earl$ onset) adj6 (DM or DM1)).ti,ab.
13. ((keto$ prone or autoimmun$ or auto immun$ or sudden onset) adj6 (DM or DM1)).ti,ab.
14. ((keto$ resist$ or nonketo$ or non keto$ or adult$ onset or matur$ onset or late$ onset or slow onset or stabl$) adj6 (DM or DM2)).ti,ab.
15. exp Insulin Resistance/
16. (insulin$ defic$ adj6 (absolut$ or relativ$)).ti,ab.
17. metabolic$ syndrom$.ti,ab.
18. (syndrom$ X not (fragil$ X or X linked)).ti,ab.
19. (plurimetabolic$ syndrom$ or pluri metabolic$ syndrom$).ti,ab.
20. or/1-19
21. exp Psychotherapy/
22. exp Counseling/
23. exp Mood disorders/
24. exp Depression/
25. psycho$.mp
26. counsel$.mp
27. depression.mp
28. depressive.mp
29. (interpersonal adj5 therap$).mp
30. art therap$.mp
31. aversion therap$.mp

32. balint.mp
33. behavio?r adj5 (intervention or therap* or modific*)
34. cognitive adj5 (therap* or intervention or program* or train* or theory)
35. (family adj3 (intervention or treatment or counsel* or therap*)
36. colo?r therap$.mp.
37. crisis intervention.mp
38. dance therap$.mp
39. gestalt therap$.mp
40. music therap$.mp
41. milieu therap$.mp
42. (assert$ adj5 training).mp
43. Narrative therap$.mp.
44. nondirective therap$.mp
45. (problem solving adj5 therap$).mp
46. (self control adj5 therap$).mp
47. person cent$.mp
48. client cent$.mp
49. psychodrama$.mp
50. paradoxical technique$.mp
51. play therap$.mp
52. rational emotive.mp
53. reality therap$.mp
54. role play$.mp
55. (relax$ adj5 training).mp
56. sociotherap$.mp
57. socioenvironmental.mp
58. supportive therap$.mp
59. transactional.mp
60. acceptance adj2 (commitment therap*)
61. coping skills training.mp.
62. exp Mindfulness/
63. motivation* adj2 (interview* or therap*)
64. multisystemic therapy
65. or/21-64
66. Randomized Controlled Trials as Topic/
67. randomized controlled trial/
68. Random Allocation/
69. Double Blind Method/
70. Single Blind Method/
71. clinical trial/
72. clinical trial, phase i.pt
73. clinical trial, phase ii.pt
74. clinical trial, phase iii.pt
75. clinical trial, phase iv.pt
76. controlled clinical trial.pt
77. randomized controlled trial.pt

78. multicenter study.pt
79. clinical trial.pt
80. exp Clinical Trials as topic/
81. (clinical adj25 trial$).tw
82. ((singl$ or doubl$ or treb$ or tripl$) adj25 (blind$3 or mask$3)).tw
83. PLACEBOS/
84. placebo$.tw
85. randomly allocated.tw
86. (allocated adj2 random$).tw
87. Or/66-86
88. case report.tw
89. letter/
90. historical article/
91. Or/ 88-90
92. 87 NOT 91
93. 20 AND 65 AND 92
94. limit 88 to yr="2003 -Current"

PsychINFO

	Diabetes		**Psych interventions**		**Clinical trials (Watson et al, 1999)**
1	exp diabetes/	16	exp psychotherapy/	65	reatment effectiveness evaluation/
2	diabet$.ab,ti.	17	exp cognitive therapy/	66	exp Treatment Outcomes/
3	(DKA or IDDM).mp. or DMI.ab,ti. [mp=title, original title, abstract, name of substance word, subject heading word]	18	Exp major depression/	67	exp Psychotherapeutic Outcomes/
4	(MODY or DM2 or NIDDM).mp. or IIDM.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]	19	exp mindfulness/	68	PLACEBO/
5	insulin$ secret$ dysfunc$.ti,ab.	20	exp psychotherapeutic techniques/	69	exp Followup Studies/
6	insulin$ resist$.ti,ab.	21	exp Problem Solving/	70	placebo$.tw.
7	((impaired glucose tolerance or glucose intoleran$ or insulin$ resist$) and (DM or DM2)).ti,ab.	22	exp counseling/	71	random$.tw.
8	insulin$ depend$.mp. or insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]	23	exp psychoeducation/	72	comparative stud$.tw.
9	(non insulin$ depend$ or nonisulin$ depend$ or nonisulin?depend).mp. or non insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]	24	Psycho*.mp	73	randomi#ed controlled trial$.tw.
10	(("typ$ 1" or typ$ I) adj6 DM).ti,ab.	25	Counsel*.mp	74	(clinical adj3 trial$).tw.
11	(("typ$ 2" or typ$ II) adj6 DM).ti,ab.	26	depression.mp	75	(research adj3 design).tw.

12	((juvenil$ or child$ or keto$ or labil$ or brittl$ or earl$ onset) adj6 (DM or DM1)).ti,ab.	27	depressive.mp	76	(evaluat$ adj3 stud$).tw.
13	((keto$ prone or autoimmun$ or auto immun$ or sudden onset) adj6 (DM or DM1)).ti,ab.	28	(interpersonal adj5 therap$).mp	77	(prospectiv$ adj3 stud$).tw.
14	((keto$ resist$ or nonketo$ or non keto$ or adult$ onset or matur$ onset or late$ onset or slow onset or stabl$) adj6 (DM or DM2)).ti,ab.	29	art therap$.mp	78	((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or madk$)).tw.
	Insulin Resistance.mp.	30	aversion therap$.mp	79	Limit 2003-current
	(insulin$ defic$ adj6 (absolut$ or relativ$)).ti,ab.	31	balint.mp		
	metabolic$ syndrom$.ti,ab.	32	behavio?r adj5 (intervention or therap* or modific*)		
	(syndrom$ X not (fragil$ X or X linked)).ti,ab.	33	cognitive adj5 (therap* or intervention or program* or train* or theory)		
		34	family adj3 (intervention or treatment or counsel* or therap*)		
		35	colo?r therap$.mp.		
		36	crisis intervention.mp		
		37	dance therap$.mp		
		38	gestalt therap$.mp		

		39	music therap$.mp		
		40	milieu therap$.mp		
		41	(assert$ adj5 training).mp		
		42	Narrative therap$.mp.		
		43	nondirective therap$.mp		
		44	(problem solving adj5 therap$).mp		
		45	(self control adj5 therap$).mp		
		46	person cent$.mp		
		47	client cent$.mp		
15	Or/1-14	48	psychodrama$.mp		
		49	paradoxical technique$.mp		
		50	play therap$.mp		
		15	rational emotive.mp		
		52	reality therap$.mp		
		53	role play$.mp		
		54	(relax$ adj5 training).mp		
		55	sociotherap$.mp		

		56	socioenvironmental.mp		
		57	supportive therap$.mp		
		58	transactional.mp		
		59	acceptance adj2 (commitment therap*)		
		60	coping skills training.mp.		
		61	exp Mindfulness/		
		62	motivation* adj2 (interview* or therap*)		
		63	multisystemic therapy		
		64	Or/16-63		

Cochrane Controlled Trials

Keyword	**Diabetes mellitus**		**Psychological therapies**		**Clinical trials**
1	MeSH descriptor: [Diabetes Mellitus] explode all trees	18	MeSH descriptor: [Psychotherapy] explode all trees	61	Limit to 'trials' Limit to '2003-current'
2	diabet*:ti,ab	19	MeSH descriptor: [Problem Solving] explode all trees	62	
3	DKA or IDDM	20	MeSH descriptor: [Depression] explode all trees	63	
4	dmi:ti,ab	21	MeSH descriptor: [Stress, Psychological] explode all trees	64	
5	mody or dm2 or niddm	22	MeSH descriptor: [Counseling] explode all trees	65	
6	(iidm):ti,ab	23	psycho*	66	
7	insulin* next secret* next dysfunc*	24	counsel*	67	
8	(insulin* next resist*):ti,ab	25	depression	68	
9	((impaired next glucose next tolerance) or (glucose next intoleran*) or (insulin* next resist*):ti) and (DM:ti,ab or DM2:ti,ab)	26	depressive	69	
10	((juvenile* or child* or keto* or labil* or brittl* or "early onset") and (diabetes or DM or DM1))	27	(interpersonal NEAR/5 therap*)	70	
11	(("keto* prone" near/6 diabet*) or (autoimmun* near/6 diabet*) or ("auto immun*" near/6 diabet*) or ("sudden onset" near/6 diabet*))	28	art therap*	71	

12	((keto* and (resist* near/6 diabet*)) or (nonketo* near/6 diabet*) or (non and (keto* near/6 diabet*)) or (adult* and (onset near/6 diabet*)) or (matur* and (onset near/6 diabet*)) or (late* and (onset near/6 diabet*)) or (slow* and (onset near/6 diabet*)) or (stabl* near/6 diabet*))	29	aversion therap*	72	
13	MeSH descriptor: [Insulin Resistance] explode all trees	30	balint	73	
14	("insulin* depend*" or "noninsulin* depend*" or "non insulin-depend*" or (typ* and (I near/6 diabet*)) or (typ* and (II near/6 diabet*)))	31	behavio?r near/5 (intervention or therap* or modific*)	74	
15	((insulin* and (defic* near/6 absolut)) or (insulin* and (defic* near/6 relativ*)))	32	cognitive near/5 (therap* or intervention or program* or train* or theory)	75	
16	((metabolic* and syndrom*:ti) or (metabolic* and syndrom*:ab) or (plurimetabolic* and syndrom*:ti) or (plurimetabolic* and syndrom*:ab) or (pluri and metabolic* and syndrom*:ti) or (pluri and metabolic* and syndrom*:ab))	33	family near/3 (intervention or treatment or counsel* or therap*)	76	
17	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16	34	colo?r therap*	77	
		35	crisis intervention	78	
		36	dance therap*	79	
		37	gestalt therap*	80	
		38	music therap*	81	
		39	milieu therap*	82	

		40	assert* near/5 training	83	
		41	Narrative therap*	84	
		42	nondirective therap*	85	
		43	problem solving near/5 therap*	86	
		44	self control near/5 therap*	87	
		45	person cent*	88	
		46	client cent*	89	
		47	psychodrama*		
		48	paradoxical technique*		
		49	play therap*		
		50	rational emotive		
		51	reality therap*		
		52	role play*		
		53	relax* near/5 training		
		54	sociotherap*		
		55	socioenvironmental		
		56	supportive therap*		
		57	transactional		
		58	acceptance near/2 (commitment therap*)		
		59	coping skills training		
		60	motivation* near/2 (interview* or therap*)		
		61	multisystemic therapy		
		62	#18 of #19 or #20 or #21 or #22 or #23 or		

			#24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58 or #59 or #60 or #61		

CINAHL

	Diabetes		Psych interventions		Clinical trials
1	MH "DIABETES MELLITUS+"	30	(MH "Psychotherapy+")	72	(MH "Clinical Trials+")
2	TI diabet*	31	(MH "Counseling+")	73	PT Clinical trial
3	AB diabet*	32	(MH "Affective Disorders+")	74	TX clinic* n1 trial*
4	DKA or IDDM or TI DMI or AB DMI	33	TX Psycho*	75	TX ((singl* n1 blind*) or (singl* n1 mask*)) or TX ((doubl* n1 blind*) or (doubl* n1 mask*)) or TX ((tripl* n1 blind*) or (tripl* n1 mask*)) or TX ((trebl* n1 blind*) or (trebl* n1 mask*))
5	MODY or DM2 or NIDDM or TI IDDM or AB IDDM	34	TX Counsel*	76	TX randomi* control* trial*
6	TI insulin* secret* dysfunc* or AB insulin* secret* dysfunc*	35	TX depress*	77	(MH "Random Assignment")
7	TI insulin* resist* or AB insulin* resist*	36	TX (interpersonal n5 therap*)	78	TX random* allocat*
8	impaired glucose tolerance or glucose intoleran* or insulin* resist*	37	TX Interpersonal therapy	79	TX placebo*
9	TI DM or AB DM or TI DM2 or AB DM2	38	TX art therap*	80	(MH "Placebos")
10	S9 and S8	39	TX aversion therap*	81	(MH "Quantitative Studies")
11	insulin* depend* or AB insulin* depend* or TI insulin* depend*	40	TX balint	82	TX allocat* random*
12	TX non insulin* depend* or nonisulin* depend* or non isulin* depend*	41	TX behavio#r n5 (intervention or therap* or modific*)	83	S72 OR S73 OR S74 OR S75 OR S76 OR S77 OR S78 OR S79 OR S80 OR S81 OR S82

13	"typ* 1" or "typ* I"	42	TX cognitive n5 (therap* or intervention or program* or train* or theory)	84	S29 AND S71 AND S83
14	TI DM or AB DM	43	TX Colo#r therap*	85	
15	S14 and S13	44	TX (family n3 (intervention or treatment or counsel* or therap*)		
16	"typ* 2" or "typ* II"	45	TX crisis intervention		
17	S16 and S14	46	TX dance therap*		
18	TI DM or AB DM or TI DM1 or AB DM1	47	TX gestalt therap*		
19	TX juvenil* or child* or keto* or labil* or brittl* or "earl* onset"	48	TX music therap*		
20	S19 and S18	49	TX milieu therap*		
21	TX keto* prone or autoimmun* or auto immun* or "sudden onset"	50	TX (assert* n5 training)		
22	S21 and S18	51	TX nondirective therap*		
23	TX keto resist* or nonketo* or non keto* or "adult* onset" or matur* or "late* onset" or "slow onset" or stabl*	52	TX (problem solving n5 therap*)		
24	S23 and S18	53	TX (self control n5 therap*)		
25	MH INSULIN RESISTANCE	54	TX person cent*		
26	insulin* defic*	55	TX client cent*		
27	TI metabolic* syndrom* or AB metabolic* syndrom*	56	TX Psychodrama*		
28	syndrom* X not (fragil* X or X linked)	57	TX paradoxical technique*		

29	S28 or S27 or S26 or S25 or S24 or S22 or S20 or S17 or S15 or S12 or S11 or S10 or S7 or S6 or S5 or S4 or S3 or S2 or S1	58	TX play therap*		
		59	TX rational emotive		
		60	TX reality therap*		
		61	TX role play*		
		62	TX (relax* n5 training)		
		63	TX Sociotherap*		
		64	TX socioenvironmental		
		65	TX supportive therap*		
		66	TX transactional		
		67	TX coping skills training		
		68	TX mindfulness		
		69	TX acceptance n2 (commitment therap*)		
		70	TX motivation* n2 (interview* or therap*)		
		71	Or / S30-S72		

EMBASE

EMBASE search strategy

	Diabetes mellitus		**Psychological interventions**		**Clinical trials**
1	exp Diabetes Mellitus/	21	exp Psychotherapy/	69	Clinical trial/

2	diabet$.ab,ti.	22	exp Counseling/	70	Randomized controlled trial/
3	(DKA or IDDM).mp. or DMI.ab,ti.	23	exp Mood disorders/	71	Randomization/
4	(MODY or DM2 or NIDDM).mp. or IIDM.ti,ab.	24	exp Depression/	72	Single blind procedure/
5	insulin$ secret$ dysfunc$.ti,ab.	25	psycho$.mp.	73	Double blind procedure/
6	insulin$ resist$.ti,ab.	26	counsel$.mp.	74	Crossover procedure/
7	((impaired glucose tolerance or glucose intoleran$ or insulin$ resist$) and (DM or DM2)).ti,ab.	27	depression.mp.	75	Placebo/
8	insulin$ depend$.mp. or insulin?depend$.ti,ab.	28	depressive.mp.	76	Randomi?ed controlled trial$.tw.
9	(non insulin$ depend$ or nonisulin$ depend$ or nonisulin?depend).mp. or non insulin?depend$.ti,ab.	29	(interpersonal adj5 therap$).mp.	77	Rct.tw.
10	(("typ$ 1" or typ$ I) adj6 DM).ti,ab.	30	art therap$.mp.	78	Random allocation.tw.
11	(("typ$ 2" or typ$ II) adj6 DM).ti,ab.	31	aversion therap$.mp.	79	Randomly allocated.tw.
12	((juvenil$ or child$ or keto$ or labil$ or brittl$ or earl$ onset) adj6 (DM or DM1)).ti,ab.	32	balint.mp.	80	Allocated randomly.tw.
13	((keto$ prone or autoimmun$ or auto immun$ or sudden onset) adj6 (DM or DM1)).ti,ab.	33	colo?r therap$.mp.	81	(allocated adj2 random).tw.
14	((keto$ resist$ or nonketo$ or non keto$ or adult$ onset or matur$ onset or late$ onset or slow onset or stabl$) adj6 (DM or DM2)).ti,ab.	34	crisis intervention.mp.	82	Single blind$.tw.

15	exp Insulin Resistance/	35	dance therap$.mp.	83	Double blind$.tw.
16	(insulin$ defic$ adj6 (absolut$ or relativ$)).ti,ab.	36	gestalt therap$.mp.	84	((treble or triple) adj blind$).tw.
17	metabolic$ syndrom$.ti,ab.	37	music therap$.mp.	85	Placebo$.tw.
18	(syndrom$ X not (fragil$ X or X linked)).ti,ab.	38	milieu therap$.mp.	86	Prospective study/
19	(plurimetabolic$ syndrom$ or pluri metabolic$ syndrom$).ti,ab.	39	(assert$ adj5 training).mp.	87	Or /69-86
20	or/1-19	40	Narrative therap$.mp.	88	Case study/
		41	nondirective therap$.mp.	89	Case report.tw.
		42	(problem solving adj5 therap$).mp.	90	Abstract report/ or letter/
		43	(self control adj5 therap$).mp.	91	Or /88-90
		44	person cent$.mp.	92	87 NOT 91
		45	client cent$.mp.	93	Limit 2003-current
		46	psychodrama$.mp.		
		47	paradoxical technique$.mp.		
		48	play therap$.mp.		
		49	rational emotive.mp.		
		50	reality therap$.mp.		
		51	role play$.mp.		
		52	(relax$ adj5 training).mp.		
		53	sociotherap$.mp.		
		54	socioenvironmental.mp.		
		55	supportive therap$.mp.		
		56	transactional.mp.		
		57	(behavio?r adj5 (intervention or therap* or modific*)).mp.		
		58	coping skills training.mp.		
		59	(family adj3 (intervention or treatment or counsel* or therap*)).mp.		
		60	exp Mindfulness/		
		61	multisystemic therapy.mp.		
		62	(acceptance adj2		

			commitment therap*).mp.		
		63	(motivation* adj2 (interview* or therap*)).mp.		
		64	(cognitive adj5 (therap* or intervention or program* or train* or theory)).mp.		
		65	problem solving/		
		66	stress management/		
		67	mindfulness.mp.		
		68	Or /21-68		

Web of Science

Keyword	**Diabetes mellitus**		**Psychological therapies**		**Clinical trials**
1	TI=(diabet*)	21	TS=Psycho*	63	TS=Random*
2	TS=(DKA or IDDM)	22	TS=Counsel*		
3	TS=(MODY or DM2 or NIDDM)	23	TS=Depression		
4	TS=(insulin* secret* dysfunc*)	24	TS=Depressive		
5	TS=(insulin* resist*)	25	TS=(interpersonal NEAR/5 therap*)		
6	TS=((impaired glucose tolerance or glucose intoleran* or insulin* resist*) and (DM or DM2))	26	TS=(art therap*)		
7	TS=(insulin* depend*)	27	TS=(aversion therap*)		
8	TS=(non insulin* depend* or nonisulin* depend* or nonisulin?depend)	28	TS=balint		
9	TS=(non insulin$depend*)	29	TS=((behavio?r) NEAR/5 (intervention or therap* or modific*))		
10	TI=(("typ* 1" or "typ* I") NEAR/6 (DM))	30	TS=((cognitive) NEAR/5 (therap* or intervention or program* or train* or theory))		
11	TI=(("typ* 2" or "typ* II") NEAR/6 (DM))	31	TS=((family) NEAR/3 (intervention or treatment or counsel* or therap*))		
12	TS=((juvenil* or child* or keto* or labil* or brittl* or "earl* onset") NEAR/6 (DM or DM1))	32	TS=(colo?r therap*)		

13	TS=(("keto* prone" or autoimmun* or "auto immun*" or "sudden onset") NEAR/6 (DM or DM1))	33	TS=(crisis intervention)		
14	TS=(("keto* resist*" or nonketo* or "non keto*" or "adult* onset" or "matur* onset" or "late* onset" or "slow onset" or stabl*) NEAR/6 (DM or DM2))	34	TS=(dance therap*)		
15	TS=Insulin Resistance	35	TS=(gestalt therap*)		
16	TS=((insulin* defic*) NEAR/6 (absolut* or relativ*))	36	TS=(music therap*)		
17	TS= metabolic* syndrom*	37	TS=(milieu therap*)		
18	TS=((syndrom* X) not (fragil* X or X linked))	38	TS=(assert* NEAR/5 training)		
19	TS=(plurimetabolic* syndrom* or pluri metabolic* syndrom*)	39	TS=(Narrative therap*)		
20	#19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1	40	TS=(nondirective therap*)		
		41	TS=(problem solving NEAR/5 therap*)		
		42	TS=(self control NEAR/5 therap*)		
		43	TS=(person cent*)		
		44	TS=(client cent*)		
		45	TS=psychodrama*		
		46	TS=(paradoxical technique*)		
		47	TS=(play therap*)		

		48	TS=(rational emotive)		
		49	TS=(reality therap*)		
		50	TS=(role play*)		
		51	TS=(relax* NEAR/5 training)		
		52	TS=sociotherap*		
		53	TS=socioenvironmental		
		54	TS=(supportive therap*)		
		55	TS=transactional		
		56	TS=((acceptance) NEAR/2 (commitment therap*))		
		57	TS=(coping skills training)		
		58	TS=Mindfulness		
		59	TS=((motivation*) NEAR/2 (interview* or therap*))		
		60	TS=(multisystemic therapy)		
		61	TS=(stress management)		
		62	Or /21-61		

Appendix II: MITI Version 3.0

Revised Global Scales: Motivational Interviewing Treatment Integrity 3.0 (MITI 3.0)

T.B. Moyers, T. Martin, J.K. Manuel, W.R. Miller, & D. Ernst
University of New Mexico
Center on Alcoholism, Substance Abuse and Addictions (CASAA)

Author Note: The Motivational Interviewing Treatment Integrity (MITI) Code is an instrument-in-development. We are making it available now for use in research and scholastic endeavors, and we expect that many improvements will be needed before this coding system is complete. If you find errors, inconsistencies or have suggestions for improvement or other feedback, please contact us. We look forward to improving the MITI, with your help.

Theresa Moyers, Ph.D. (tmoyers@unm.edu)

Learn, compare, collect the facts!
Pavlov 1849-1936

How well or poorly is a practitioner using motivational interviewing? The MITI is a behavioral coding system that provides an answer to this question. The MITI also yields feedback that can be used to increase clinical skill in the practice of motivational interviewing. The MITI is intended to be used: 1) as a treatment integrity measure for clinical trials of motivational interviewing and 2) as a means of providing structured, formal feedback about ways to improve practice in non-research settings.

It should be noted that the MITI and its parent instrument, the Motivational Interviewing Skills Code (MISC), are not competing instruments for the same task. They are different tools designed to accomplish different tasks. The MISC is typically more useful in conducting detailed process research investigating the critical elements and causal mechanisms within motivational interviewing. It cannot be replaced by the MITI for these purposes. Alternatively, the MITI may be more useful when a simpler question is posed (how much is this treatment like motivational interviewing?) or when more targeted feedback is needed (how can our clinicians improve in their use of motivational interviewing?) for training. Specific differences between the MITI and the MISC are:

1) The MISC provides a comprehensive examination of interviewer and client behaviors, as well as the interaction between the two, while the MITI measures only interviewer behaviors.
2) The MISC may require up to three separate reviews or "passes" of the tape segment, while the MITI typically uses a single pass.
3) The MISC captures dimensions of the client's readiness to change and commitment language, while the MITI does not. Such client behavior can be important in predicting outcomes.
4) The MISC is a mutually exclusive and exhaustive coding system, but the MITI is not. Many specific behaviors that are coded in the MISC are collapsed into a single category in the MITI, or left uncoded entirely.

A. COMPONENTS OF THE MITI

The MITI has two components: the global scores and the behavior counts.

A global score requires the coder to assign a single number from a five-point scale to characterize the entire interaction. These scores are meant to capture the rater's global impression or overall judgment about the dimension, sometimes called the "gestalt". Five global dimensions are rated: Evocation, Collaboration, Autonomy/Support, Direction, and Empathy. This means that each MITI review will contain five global scores.

A behavior count requires the coder to tally instances of particular interviewer behaviors. These running tallies occur from the beginning of the segment being reviewed until the end. The coder is not required to judge the quality or overall adequacy of the event, as with global scores, but simply to count it.

Typically both the global scores and behavior counts are assessed within a single review of the tape, and typically a random 20-minute segment is used. Careful attention should be paid to ensuring that the sampling of the tape segments is truly random, especially within clinical trials, so that proper inferences about the overall integrity of the MI intervention can be drawn.

The tape may be stopped as needed, however excessive stopping and restarting in actual coding (as opposed to training or group review) may disrupt the ability of the coder to form a gestalt impression needed for the global codes. Coders may therefore decide to use two passes through the tape until they are proficient in using the coding system. In that case, Pass One should be used for the global scores and Pass Two for the behavior counts.

B. DESIGNATING A TARGET BEHAVIOR

An important component of using motivational interviewing well involves the interviewer's attention to facilitating change of a particular behavior or problem. Skillful interviewers will attempt to reinforce and elicit client change talk about that specific change when they can. Coders should know, in advance of the coding task, what is the designated target behavior for the intervention, assuming that there is one. This will allow coders to judge more accurately whether the clinician is directing interventions toward the target behavior, is floundering or hopelessly lost. The MITI is not designed to be used for interventions in which a target behavior cannot be identified.

C. GLOBAL SCORES

"What is the short meaning of a long speech?"
Schiller (1759-1805)

Global scores are intended to capture the rater's overall impression of how well or poorly the interviewer meets the intent of the scale. While this may be accomplished by simultaneously evaluating a variety of elements, the rater's gestalt or all-at-once judgment is paramount. The global scores should reflect the holistic evaluation of the interviewer, one that cannot necessarily be separated into individual elements. Global scores are given on a five-point Likert scale, with the coder assuming a beginning score of "3" and moving up or down from there.

In the MITI 3.0, the Spirit global rating has been parsed into three global ratings: Evocation, Collaboration, and Autonomy/Support. These ratings are not orthogonal; rather they may be related and influenced by each other. Evocation, Collaboration, and Autonomy/Support are averaged together to yield a Spirit global. It is recommended that you average to two decimal points.

Evocation				
Low				High
1	2	3	4	5
Clinician actively provides reasons for change, or education about change, in the absence of exploring client's knowledge, efforts or motivation.	Clinician relies on education and information giving at the expense of exploring client's personal motivations and ideas.	Clinician shows no particular interest in, or awareness of, client's own reasons for change and how change should occur. May provide information or education without tailoring to client circumstances.	Clinician is accepting of client's own reasons for change and ideas about how change should happen when they are offered in interaction. Does not attempt to educate or direct if client resists.	Clinician works proactively to evoke client's own reasons for change and ideas about how change should happen.

This scale is intended to measure the extent to which the clinician conveys an understanding that motivation for change, and the ability to move toward that change, reside mostly within the client and therefore focuses efforts to elicit and expand it within the therapeutic interaction.

Low on Scale

Clinicians low on this scale have only superficial interest in the client's ambivalence or reasons for change, and miss opportunities to explore these in detail. They may make assumptions about the client's intent to change (or not change) without exploring this in detail, or may ignore the client's ideas when they are offered. Clinicians low in *Evocation* may rely on persistent fact gathering or information-giving as a means of facilitating change, and often convey a distrust of the client's current knowledge base about the problem under consideration. Clinicians on the low end of this scale do not respond to change talk when it is offered, or do so in a perfunctory manner. They are likely to *provide* the clients with reasons to change, rather than *eliciting* them.

High on Scale

Clinicians high on this scale are curious about their clients' personal and unique ideas about why change is a good idea or might not be. They not only follow up on these ideas when the client offers them, but also actively seek to explore them when the client does not. Although they might provide information or education, clinicians high in evocation do not rely on it as a means of helping clients to change. Instead, they prioritize exploration of the client's personal reasons for change and the means to go about it, and do not allow this exploration to be neglected amid other content or information in the session. Clinicians high on the

Evocation scale understand the value of hearing the client's own language in favor of change, and actively create opportunities for that language to occur.

Verbal Anchors

1. Clinician actively provides reasons for change, or education about change, in the absence of exploring client's knowledge, efforts or motivation.

Examples:

- Ignores or misunderstands client statements about target behavior
- Rigidly provides education although client indicates prior knowledge
- Uses list of questions that do not account for uniqueness of client's response
- Dismisses or ignores client contributions
- Lack of curiosity about client circumstances
- Attempts to talk client into changing

2. Clinician relies on education and information giving at the expense of exploring client's personal motivations and ideas.

Examples:

- Does not incorporate client contributions into discussions about change
- Vague or incomplete efforts to respond to client change talk
- Mild or superficial interest in client views and circumstances

3. Clinician shows no particular interest in or awareness of client's own reasons for change and how change should occur. May provide some information or education without tailoring to client circumstances.

Examples:

- Misses opportunities to investigate client motivation for change (for example, by discussing past successes when mentioned)
- Neutral regarding client views and circumstances
- Occasional responses to client change talk

4. Clinician is accepting of client's own reasons for change and ideas about how change should happen when they are offered in interaction. Does not attempt to educate or direct if client resists.

Examples:

- Permits client's ideas about change and motivation to provide direction for interview
- Acknowledges client reasons for change at face value when offered, but does not elicit or elaborate
- Consistently responds to change talk when it occurs with reflections, elaborating questions or interest

5. Clinician works proactively to evoke client's own reasons for change and ideas about how change should happen.

Examples:

- Curious about client's ideas and experiences, especially regarding target behavior
- Helps client talk self into changing
- Uses structured therapeutic tasks as a way of reinforcing and eliciting change talk
- Does not miss opportunities to explore more deeply when client offers reasons for change
- Seeks client's ideas about change and motivation to provide direction to interview
- Strategically elicits change talk and consistently responds to it when offered

Collaboration				
Low				High
1	2	3	4	5
Clinician actively assumes the expert role for the majority of the interaction with the client. Collaboration is absent.	Clinician responds to opportunities to collaborate superficially.	Clinician incorporates client's goals, ideas and values but does so in a lukewarm or erratic fashion. May not perceive or may ignore opportunities to deepen client's contribution to the interview.	Clinician fosters collaboration and power sharing so that client's ideas impact the session in ways that they otherwise would not.	Clinician actively fosters and encourages power sharing in the interaction in such a way that client's ideas substantially influence the nature of the session.

This scale measures the extent to which the clinician behaves as if the interview is occurring between two equal partners, both of whom have knowledge that might be useful in the problem under consideration.

Low on Scale

Clinicians low in *Collaboration* do not work towards a mutual understanding during the session. They rely on one-way communication based on the clinician's authority and expertise for progress. They may be dismissive, overly passive or so acquiescent that they do not make a genuine contribution to the interaction. These clinicians rely on their knowledge to respond to the client's problem and do not appear to value the client's knowledge. They are often ahead

of their clients in prescribing both the need for change and the means to achieve it. Their interactions with clients appear more like wrestling than dancing.

High on Scale

Clinicians high in *Collaboration* work cooperatively with the client toward the goals of the interview. They do not rely on dominance, expertise or authority to achieve progress. They are curious about client ideas, and are willing to be influenced by them. These clinicians can hold the reins on their own expertise, using it strategically and not before the client is ready to receive it. Clinicians high in *Collaboration* appear to be dancing with their clients during an interview—one moment leading, the next following—in seamless motion.

Verbal Anchors

1. Clinician actively assumes the expert role for the majority of the interaction with the client. Collaboration is absent.

Examples:

- Explicitly takes the expert role
- Denies or minimizes client ideas
- Dominates conversation
- Argues when client offers alternative approach
- Is passive, disconnected or dismissive

2. Clinician discourages collaboration or responds to opportunities superficially.

Examples:

- Difficulty surrendering expert role
- Superficial querying of client input
- Often sacrifices opportunities for mutual problem solving in favor of supplying knowledge or expertise
- Minimal response to client input
- Distracted or impatient with client

3. Clinician incorporates client's goals, ideas and values but does so in a lukewarm or erratic fashion. May not perceive or may ignore opportunities to deepen client's contribution to the interview.

Examples:

- May take advantage of opportunities to collaborate, but does not structure interaction to solicit this
- Some connected following, but superficial
- Can yield floor most of the time, but instances of disagreeing
- Sacrifices some opportunities for mutual problem solving in favor of supplying knowledge or expertise

4. Clinician fosters collaboration and power sharing so that client's ideas impact the session in ways that they otherwise would not.

Examples:

- Some structuring of session to insure client input
- Solicits client views
- Engages client in problem solving
- Does not insist on resolution unless client is ready

5. Clinician actively fosters and encourages power sharing in the interaction in such a way that client's ideas substantially influence the direction and outcome of the session.

Examples:

- Actively structures session in a manner that facilitate client input
- Querying client ideas
- Incorporating client suggestions
- Actively "mines" for client input
- Explicitly identifying client as the expert

Tempers advice giving and expertise depending on client input

Autonomy/Support				
Low				High
1	2	3	4	5
Clinician actively detracts from or denies client's perception of choice or control.	Clinician discourages client's perception of choice or responds to it superficially.	Clinician is neutral relative to client autonomy and choice.	Clinician is accepting and supportive of client autonomy.	Clinician adds significantly to the feeling and meaning of client's expression of autonomy, in such a way as to *markedly expand client's experience of own control and choice.*

This scale is intended to convey the extent to which the clinician supports and actively fosters client perception of choice as opposed to attempting to control the client's behavior or choices. Scores on the autonomy scale include the avoidance of particular behaviors *and* proactively pursuing strategies to enhance autonomy or support.

Low on Scale

Clinicians low on *Autonomy/Support* view the client as incapable of moving in the direction of health without input from clinician. They may assume that the client will change their behavior in the direction that the clinician thinks is best. The clinician may explicitly tell that client that he or she has no choice. In addition, the clinician may imply that external consequences (such as arrest, coercion from others) have removed choice. Clinicians may also insist that there is only one way to approach a target behavior or they may be pessimistic or cynical about the client's ability to change. Clinicians low on *Autonomy/Support* may convey choices but do so dismissively or with sarcasm.

*Note: Do *not* lower Autonomy/Support scores if the clinician is empathizing with the client's perceived lack of choices, hopelessness or resentment about current circumstance.

High on Scale

Clinicians high on *Autonomy/Support* ensure, either directly or implicitly, that the topic of choice and control is raised in session. They view the client as having the potential to move in the direction of health. Clinicians high on this scale work to help the client recognize choices with regard to the target behavior. In addition, clinicians may explicitly acknowledge that the client has the choice to change or maintain the status quo. They may also express an optimism about the client's ability to change.

Verbal Anchors

1. Clinician actively detracts from or denies client's perception of choice or control.

Examples:

- Explicitly states that client does not have a choice
- Implies that external consequences remove choice
- Is pessimistic, cynical or sarcasm in exploring options and choices
- Rigid about change options

2. Clinician discourages client's perception of choice or responds to it superficially.

Examples:

- Does not elaborate or attend to topic of choice when raised by client
- Minimizing client choice or superficially attending to it
- Dismissing topic of choice after acknowledging it
- Absence of genuineness when discussing client's choice
- Actively ignores client choice when client brings it up

3. Clinician neutral relative to client autonomy and choice.

Examples:

- Does not deny options or choice, but makes little effort to actively instill it
- Does not bring up topic of choice in the interview

4. Clinician is accepting and supportive of client autonomy.

Examples:

- Explores clients options genuinely
- Agrees when client states he cannot be forced to change

5. Clinician adds significantly to the feeling and meaning of client's expression of autonomy, in such a way as to *markedly expand client's experience of own control and choice.*

Examples:

- Clinician is proactive in eliciting comments from the client that lead to a greater perceived choice regarding the target behavior
- Explores options in deeply genuine and non-possessive manner
- Explicitly acknowledges client option not to change without sarcasm
- Provides multiple opportunities to discuss client's options and ability to control if client does not respond at first attempt

Gives credence to client's ideas about change and motivation

Direction				
Low				High
1	2	3	4	5
Clinician does not influence the topic or course of the session, and discussion of the target behavior is entirely in the hands of client.	Clinician exerts minimal influence on the session and misses most opportunities to direct client to the target behavior.	Clinician exerts some influence on the session, but can be easily diverted away from focus on target behavior.	Clinician generally able to influence direction of the session toward the target behavior; however, there may be lengthy episodes of wandering when clinician does not attempt to re-direct.	Clinician exerts influence on the session and generally does not miss opportunities to direct client toward the target behavior or referral question.

This scale measures the degree to which clinicians maintain appropriate focus on a specific target behavior or concerns directly tied to it. Unlike the other global scales, clinicians high scores on this scale do not necessarily reflect better use of MI.

Low on Scale

Clinicians low in *Direction* exert little influence concerning the topic and course of the session. They do not appear to explore any particular behavior change on the part of the client, and do not take opportunities to bring change into the discussion. Sessions with clinician low in *Direction* may lack structure, and are likely to have an aimless quality. Clients may end up discussing any topic of interest to them, without attempts by the clinician to focus on any particular troublesome behavior. The clinician may accept an excessive focus on historical topics or theoretical explanations that divert attention from changing a current behavior. Clinicians low in *Direction* appear to lack a compass to help them move the session toward to a specific, desirable end.

High on Scale

Clinicians high in *Direction* exert substantial influence concerning the topic and course of the session. They are transparent in their focus on a target behavior or referral question and they make consistent efforts to return to the target behavior when conversation wanders. A clinician who is domineering and unyielding in their focus on the problem at hand would score high in Direction, however clinicians high in *Direction* need not be harsh or authoritarian. They may exert direction by selectively reinforcing client discussion toward the possibility of concern or change with regard to the target behavior. Clinicians high in Direction seem to use a compass to implement course corrections when the focus of the session drifts too far away from the target behavior.

Verbal Anchors

1. Clinician does not influence the topic or course of the session, and discussion of the target behavior is entirely in the hands of client.

Examples:

- Fails to provide structure for session
- Session is almost entirely focused on topics only tangentially related to a current problem

- Clinician focuses discussion on client's personality, childhood or trauma history with only superficial attention to target behavior
- Clinician engages in non-directive, client-centered listening
- Passively follows as the client wanders off in various directions
- A target behavior is not stated or cannot be inferred from the session

2. Clinician exerts minimal influence on the session and misses most opportunities to direct client to the target behavior.

Examples:
- Provides some structure, but session wanders markedly from stated intent
- Some discussion of target behavior, but majority of session is spent on other topics
- Clinician makes only superficial attempts to tie client's discourse to target behavior
- Most of the session is spent in non-directive, client-centered listening with no evidence of selective reinforcement toward consideration of target behavior

3. Clinician exerts some influence on the session, but is easily diverted away from focus on target behavior.

Examples:
- Clinician provides some structure for session, but is inconsistent in following it
- Clinician provides some selective reinforcement of client discourse regarding target behavior, but does so inconsistently
- Clinician is willing to bring up target behavior, but is easily diverted
- Clinician focuses substantial parts of session on off-target discussion
- Balance of session time spent on discussing history rather than present or future

4. Clinician generally able to influence direction of the session toward target behavior; however, there may be lengthy episodes of wandering when clinician does not attempt to re-direct.

Examples:
- Clinician makes modest attempts to use stated plan for session
- A target behavior is apparent but the clinician seems uncertain about whether to focus attention on it
- Clinician can easily be diverted by the client away from the target behavior
- Clinician misses several opportunities to turn the conversation toward the target behavior once it wanders

5. Clinician exerts influence on the session and generally does not miss opportunities to direct client toward the target behavior or referral question.

Examples:
- Agenda-setting mentions the target behavior

- Clinician is transparent in concern about the target behavior
- Clinician manages time well and transitions between therapeutic tasks smoothly
- Clinician consistently and smoothly directs the client's discourse toward change of a target behavior
- Balance of time in the session is spent discussing possible change, rather than the history of the problem
- Clinician dominates session and does not allow client to wander from target behavior

Empathy				
Low				High
1	2	3	4	5
Clinician has no apparent interest in client's worldview. Gives little or no attention to the client's perspective.	Clinician makes sporadic efforts to explore the client's perspective. Clinicians' understanding may be inaccurate or may detract from the client's true meaning.	Clinician is actively trying to understand the client's perspective, with modest success.	Clinician shows evidence of accurate understanding of client's worldview. Makes active and repeated efforts to understand client's point of view. Understanding mostly limited to explicit content.	Clinician shows evidence of deep understanding of client's point of view, not just for what has been explicitly stated but what the client means but has not yet said.

This scale measures the extent to which the clinician understands or makes an effort to grasp the client's perspective and feelings: literally, how much the clinician attempts to "try on" what the client feels or thinks. Empathy should not be confused with warmth, acceptance, genuineness, or client advocacy; these are independent of the empathy rating. Reflective listening is an important part of this characteristic, but this global rating is intended to capture all efforts that the clinician makes to understand the client's perspective and convey that understanding to the client.

Low on Scale

Clinicians low in *Empathy* show indifference or active dismissal of the client's perspective and experiences. They may probe for factual information or to pursue an agenda, but they do so to "build a case" for their point of view, rather than for the sole purpose of understanding the client's perspective. There is little effort to gain a deeper understanding of complex events and emotions, and questions asked reflect shallowness or impatience. They might express hostility toward the client's viewpoint or directly blame the client for negative outcomes.

High on Scale

Clinicians high in *Empathy* approach the session as an opportunity to learn about the client. They are curious. They spend time exploring the client's opinions and ideas about the target behavior especially. Empathy is evident when providers show an active interest in understanding what the client is saying. It can also be apparent when the clinician accurately follows or perceives a complex story or statement by the client or probes gently to gain clarity.

Verbal Anchors

1. Clinician has no apparent interest in client's worldview. Gives little or no attention to the client's perspective.

Examples:

- Asking only information-seeking questions (often with an ulterior motive)
- Probing for factual information with no attempt to understand the client's perspective

2. Clinician makes sporadic efforts to explore the client's perspective. Clinicians' understanding may be inaccurate or may detract from the client's true meaning.

Examples:

- Clinician offers reflections but they misinterpret what the client had said.
- Clinician displays shallow attempts to understand the client.

3. Clinician is actively trying to understand the client's perspective, with modest success.

Examples:

- Clinician displays average empathy to client.
- Clinician may offer a few accurate reflections, but may miss the client's point.
- Clinician makes an attempt to grasp the client's meaning throughout the session, but does so with mild success.

4. Clinician shows evidence of accurate understanding of client's worldview. Makes active and repeated efforts to understand client's point of view. Understanding mostly limited to explicit content.

Examples:

- Clinician conveys interest in the client's perspective or situation
- Clinician offers accurate reflections of what the *client has said.*
- Clinician effectively communicates understanding of the client's viewpoint.

5. Clinician shows evidence of deep understanding of client's point of view, not just for what has been explicitly stated but what the client means and has not said.

Examples:

- Clinician effectively communicates an understanding of the client *beyond* what the client says in session.
- Showing great interest in client's perspective or situation
- Attempting to "put self in client's shoes"
- Often encouraging client to elaborate, beyond what is necessary to merely follow the story
- Using many accurate complex reflections

D. BEHAVIOR COUNTS

"It has long been an axiom of mine that the little things are infinitely the most important."

Sherlock Holmes (A.Conan Doyle, 1892)
A Case of Identity

Behavior counts are intended to capture specific behaviors without regard to how they fit into the overall impression of the interviewer's use of MI. While the context of the exchange will have some influence on the rater, behavior counts will *generally* be determined as a result of categorization and decision rules (rather than attempting to grasp an overall impression). Relying on inference to determine a behavior count is to be avoided.

Parsing Interviewer Speech to Assign Behavior Codes

An utterance is defined as a complete thought. An utterance ends when one thought is completed. A new utterance begins when a new idea is introduced. One utterance can succeed another in the flow of the interviewer's speech, as with a sentence that conveys successive ideas. A client response always terminates an interviewer utterance, and the next interviewer response following client speech is therefore always a new utterance.

Not all interviewer utterances will receive behavior codes. Unlike the MISC, the MITI does not represent an exhaustive list of all possible codes; therefore, some clinician utterances will likely remain uncoded. Although they are not exhaustive, MITI codes are mutually exclusive, such that the same utterance does not receive more than one code.

Any utterance may be assigned one of six primary behavior codes. Within three categories, further sub -classification is required. As mentioned before, each

utterance receives one and only one code: the same utterance may not receive more than one code. However, consecutive utterances, even if they occur in the same sentence, may *each* receive different codes. Thus, in the course of a relatively long reply, if a clinician reflects, then confronts, then asks a question, these could each qualify for a distinct behavior count, assuming they are separate utterances (ideas).

A volley is defined as uninterrupted sequence of utterances by the interviewer. Once a behavior code is assigned once within the volley, it is not assigned again. A volley may contain only one of each behavior code.

Consider the following interviewer statement:

> Well, let me ask you this: since you've been forced to come here and since you're feeling like everyone's kind of pecking on you like a crow, there's a bunch of crows flying around pecking on you about this thing about your drinking, what would you like to do with the time you spend here? What would be helpful for you?

This statement is parsed in the following way:

> Utterance One: Well, let me ask you this: since you've been forced to come here and since you're feeling like everyone's kind of pecking on you like a crow, there's a bunch of crows flying around pecking on you about this thing with your drinking,
>
> Utterance Two: What would you like to do with the time you spend here? What would be helpful for you?

What about this interviewer statement?

> What you say is absolutely true, that it is up to you. No one makes that choice for you. No one can make that choice for you. Even if your wife wanted to decide for you, or your employer wanted to decide for you, or I wanted to decide for you; nobody can. It really is completely your own choice; how you live your life, what you do about drugs, where you're headed; so that is yours. And what I hear you struggling with is, "what do I want? Is it time for me to change things? Is this drug test a wake-up call?"

We've parsed it like this:

> Utterance One: What you say is absolutely true, that it is up to you. No one makes that choice for you. No one can make that choice for you. Even if your wife wanted to decide for you, or your employer wanted to decide for you, or I wanted to decide for you; nobody can. It really is

completely your own choice; how you live your life, what you do about drugs, where you're headed; so that is yours.

Utterance Two: And what I hear you struggling with is, "what do I want? Is it time for me to change things? Is this drug test a wake-up call?"

Behavior Codes

1. **Giving Information**

This category is used when the interviewer gives information, educates, provides feedback or discloses personal information. When the interviewer gives an opinion, without advising, this category would be used. No subcodes are assigned for giving information. Specific examples of Giving Information include:

1a. *Providing Feedback from assessment instruments*

> You indicated during the assessment that you typically drink about 18 standard drinks per week. This places you in the 96th percentile for American men your age. (Giving Information)
>
> * Note that this is not a reflection. Reviewing information contained on assessment instruments does not typically qualify as a reflection, although the reflection code MAY be given if the interviewer skillfully emphasizes or enriches the material the client has given.

1b. *Personal Feedback about the client that is not already available.*

> Your doctor tells me you've been struggling with your glycemic control. (Giving Information)
>
> I talked to your wife and she said she was really worried about your drinking. (Giving Information)

1c. *Explaining ideas or concepts relevant to the intervention*

> This homework assignment on logging your cravings is important because we know that cravings often lead to relapses. A craving is like a warning bell, telling you to do something different. (Giving Information)

1d. *Educating about a topic*

> Individuals who eat five fruits and vegetables each day reduce their cancer risk five fold. For certain kinds of cancer, like colon cancer, it's even more of a reduction. (Giving Information)
>
> If I do find that you've relapsed, I'll have to disclose that to your probation officer. (Giving Information; coder may consider MI Inconsistent instead)

Coders need not distinguish among types of Giving Information. Once the coder has decided that the behavior is either one or another item in this category, she assigns the Giving Information code without further distinction.

Differentiating Giving Information from MI Non-Adherent Behaviors
Giving information should not be confused with giving advice, warning, confronting, or directing.

> You indicated during the assessment that you typically drink about 18 standard drinks per week. This far exceeds social drinking. (MI Inconsistent)
>
> Keep track of your cravings, using this log, and bring it in next week to review with me. (Direct)
>
> Well, you are only eating two fruits per day according to this chart, even though you said you are eating five. It can be easy to deceive yourself. (Confront)
>
> It worked for me, and it will work for you if you give it a try. We need to find the right AA meeting for you. You just didn't find a good one. (Advice)

2. **Questions**

2a. *Closed Question*

This behavior code is used when the interviewer asks the client a question that can be answered with a "yes" or "no" response.

> Did you use heroin this week?
> Did you eat five fruits and vegetables this week?
> Have you been having trouble with your memory?

It is also coded when the question specifies a very restricted range or one that is intended to satisfy a questionnaire.

> How long have you been using heroin?
> How many fruits and vegetables did you eat each day this week?
> Who is the president of the United States?

2b. *Open Question*

An open question is coded when the interviewer asks a question that allows a wide range of possible answers. The question may seek information, may invite the client's perspective or may encourage self-exploration. The open question allows the option of surprise for the questioner.

"Tell me more" statements are coded as open questions unless the tone and context clearly indicate a Direct or Confront code.

> How did it go with your heroin cravings since we last met?
> Tell me about your fruit and vegetable intake this week.
> What is your take on that?

In general, stacked questions (before the client gives an answer), are coded as only one question. Sometimes a clinician will stack questions by asking an open question and then giving a series of "for example" follow up questions before the client answers. These are coded as *one* open question (not, in this case, as one open and two closed questions).

> In what ways has your drinking caused problems for you? Has it caused problems in your relationships or with your memory? What about trouble with the law or health problems? Have you felt bad about yourself? Things like that.

2c. *Questions-trying-to-be-reflections*

Occasionally the interviewer will offer a statement that otherwise meets the criteria for a reflection, but is given with an inflection at the end (thereby making it "sound like" a question). These statements are coded as Questions (either open or closed), NOT as reflections.

3. **Reflection**

This category is meant to capture reflective listening statements made by the clinician *in response to* client statements. A Reflection may introduce new meaning or material, but it essentially captures and returns to clients something about what they have just said. Reflections must be further categorized into Simple or Complex categories.

3a. *Simple Reflection*

Simple reflections typically convey understanding or facilitate client/clinician exchanges. These reflections add little or no meaning (or emphasis) to what clients have said. Simple reflections may mark very important or intense client

emotions, but do not go far beyond the client's original intent in the statement. Clinician summaries of several client statements may be coded as simple reflections *if* the clinician does not use the summary to add an additional point or direction.

3b. *Complex Reflection*

Complex reflections typically add substantial meaning or emphasis to what the client has said. These reflections serve the purpose of conveying a deeper or more complex picture of what the client has said. Sometimes the clinician may choose to emphasize a particular part of what the client has said to make a point or take the conversation in a different direction. Clinicians may add subtle or very obvious content to the client's words, or they may combine statements from the client to form summaries that are complex in nature.

Speeding Tickets
Client: This is her third speeding ticket in three months. Our insurance is going to go through the roof. I could just kill her. Can't she see we need that money for other things?
Interviewer: You're furious about this. (Reflection, Simple)
Interviewer: This is the last straw for you. (Reflection, Complex)

Controlling Blood Sugar
Interviewer: What have you already been told about managing your blood sugar levels? (Open Question)
Client: Are you kidding? I've had the classes, I've had the videos, I've had the home nurse visits. I have all kinds of advice about how to get better at this, but I just don't do it. I don't know why. Maybe I just have a death wish or something, you know? *Interviewer*: You are pretty discouraged about this. (Reflection, Simple) *Interviewer*: You haven't given it your best effort yet. (Reflection, Complex)

Mother's Independence
Client: My mother is driving me crazy. She says she wants to remain independent, but she calls me four times a day with trivial questions. Then she gets mad when I give her advice.
Interviewer: Things are very stressful with your mother. (Simple Reflection) *Interviewer*: You're having a hard time figuring out what your mother really wants. (Reflection, Complex)
Interviewer: Are you having a hard time figuring out what your mother really wants? (Closed Question)
Interviewer: What do you think your mother really wants? (Open Question)

3c. DECISION RULE: When a coder cannot distinguish between a simple and complex

reflection, the simple designation should be used. Default category: simple.

3d. *Reflection and Question in Sequence*

Sometimes the interviewer begins with a reflection, but adds a question to "check" the reliability of the reflection (either open or closed). Both elements should be coded.

> So you don't ever want to use heroin again. Is that right? (Reflection, Closed Question)
>
> Your boss said you can't work overtime anymore. What do you make of that? (Reflection, Open Question)

3e. *Reflections-Turned-Into-Questions*

Occasionally the interviewer will offer a statement that otherwise meets the criteria for a reflection, but is given with an inflection at the end (thereby making it "sound like" a question). These statements are coded as Questions (either open or closed) NOT as reflections (see 2c.).

4. **MI Adherent**

This category is used to capture particular interviewer behaviors that are consistent with a motivational interviewing approach. Coders may be tempted to code especially good examples of MI practice in one of these categories, even if they do not genuinely "fit". Instead, the coder should consider such examples within the overall rating assigned for Global Ratings, as appropriate, reserving the MI Consistent behavior counts for the designated behaviors only. The MI Adherent Category is comprised of:

4a. Asking permission before giving advice or information or asking what the client already knows or has already been told about a topic *before* giving advice or information. Permission is implied when the client asks directly for the information or advice and the clinician is answering. Indirect forms of permission can also occur, such as when the clinician invites the client to disregard the advice as appropriate.

> I have some information about how to reduce your risk of colon cancer and I wonder if I might discuss it with you. (MI Adherent)
>
> What have you already been told about drinking during pregnancy? (MI Adherent)

This may not be the right thing for you, but some of my clients have had good luck setting the alarm on their wristwatch to help them remember to check their blood sugars 2 hours after lunch. (MI Adherent)

Note: when permission is asked prior to advising, the MI Non-Adherent Code is *not* used for the subsequent advice. The entire volley is coded as MI Adherent.

4b. Affirming the client by saying something positive or complimentary. Affirming may also take the form of commenting on the client's strengths, abilities or efforts in any area (not simply related to the target behavior).

You are the kind of person that, once you make up your mind, you usually get the job done. (MI Adherent)

It's important to you to be a good parent, just like your folks were for you. (MI Adherent)

4c. Emphasizing the client's control, freedom of choice, autonomy, ability to decide.

Yes, you're right. No one can force you stop drinking. (MI Adherent)

You're the one who knows yourself best here. What do you think ought to be on this treatment plan? (MI Adherent)

The number of fruits and vegetables you choose to eat is really up to you. (MI Adherent)

You've got a point there. (MI Adherent)

4d. Supporting the client with statements of compassion or sympathy.

With the parking problems and the rain coming down, it hasn't been easy to get here. (MI Adherent)

I know it's really hard to stop drinking. (MI Adherent)

Well, there is really a lot going on for you right now. (MI Adherent)

No differentiating subcodes are assigned to the MI Adherent behaviors. The rater merely identifies them as belonging to this category and assigns the MI Adherent code.

4e. DECISION RULE: The MI Adherent code takes precedence when the utterance *clearly* falls into the MI Adherent category. When in doubt, an alternate code (for example, Open Question or Reflection) should be given.

5. **MI Non-Adherent**

This category is used to capture those interviewer behaviors that are inconsistent with a motivational interviewing approach. No differentiating subcodes are assigned to the MI Non-Adherent behaviors. The rater merely identifies them as belonging to this category and assigns the MI Non-Adherent code.

5a. Advising without permission by making suggestions, offering solutions or possible actions without first obtaining permission from the client. Language usually, but not always, includes words such as: should, why don't you, consider, try, suggest, advise, how about, you could, etc. Note that if the interviewer first obtains permission either directly or indirectly, *before* advising, the code would be different.

> What about trying to get a ride from a friend? (MI Non-Adherent)
>
> Checking your blood sugars five times a day is best in the beginning. (MI Non-Adherent)
>
> It might not be as bad as you think. People are usually civil if you give them a chance. (MI Non-Adherent)

5b. Confronting the client by directly and unambiguously disagreeing, arguing, correcting, shaming, blaming, criticizing, labeling, moralizing, ridiculing, or questioning the client's honesty. Such interactions will have the quality of uneven power sharing, accompanied by disapproval or negativity. Included here are instances where the interviewer uses a question or even a reflection, but the voice tone clearly indicates a confrontation.

Restating negative information already known or disclosed by the client can be either a confront or a reflection. Most confrontations can be correctly categorized by careful attention to voice tone and context.

> You were taking Antabuse but you drank anyway? (MI Non-Adherent)
>
> You think that is any way to treat people you love? (MI Non-Adherent)

Yes, you are an alcoholic. You might not think so, but you are. (MI Non-Adherent

Wait a minute. It says right here that your A1C is 12. I'm sorry, but there is no way you could have been counting your carbohydrates like you said if it's that high. (MI Non-Adherent)

5c. Directing the client by giving orders, commands or imperatives. The language is imperative.

Don't do that! (MI Non-Adherent)

Bring this homework back next week. (MI Non-Adherent)

You need to go to 90 meetings in 90 days (MI Non-Adherent)

Again, coders are not required to subcategorize MI Non -Adherent behaviors. Once a coder has decided that the behavior is either a Confront or a Direct (or has narrowed it down to any other two codes in this category), he assigns the MI Non-Adherent code and moves on.

5d. DECISION RULE: The MI Non-Adherent code takes precedence when the utterance *clearly* falls into the MI Non-Adherent category. When in doubt, an alternate code (for example, Giving Information) should be given.

Tantrums
Client: "What do you think I should do about these tantrums my child is having? You're the doctor."
Interviewer: "Solving this yourself hasn't worked, so you're finally willing to ask for help." (MI Non-Adherent)

Client: "What do you think I should do about these tantrums my child is having? You're the doctor."
Interviewer: "Your child is normal. These are not tantrums." (MI Non-Adherent)

E. CHOOSING THE LENGTH AND TYPE OF THE CODED SEGMENT

The development of the MITI was done using 20-minute segments of therapy tapes. It may be possible to use the MITI for longer segments of tape (for example, the entire therapy session). We only caution that our attempt to increase the length of the coding segment was associated with 1) problems with sustained coder attention, 2) difficulty forming global judgments with increased data, and 3) logistical difficulties in obtaining uninterrupted work time in a busy setting.

Similarly, most of our initial data have been gathered using audiotapes rather than videotapes. The MITI can be used to code videotapes, but should not be altered to gather visual information.

F. SUMMARY SCORES FOR THE MITI

Because critical indices of MI functioning are imperfectly captured by frequency counts, we have found that many applications of therapy coding are better served with summary scores computed from codes, rather than the individual scores themselves. For example, the ratio of reflections to questions provides a concise measure of an important MI process. Below is a partial list of summary scores that serve as outcome measures for determining competence in MI, as well as formulas for calculating them.

- Global Spirit Rating = (Evocation + Collaboration + Autonomy/Support) / 3

- Percent Complex Reflections (% CR)
  = Rc / Total reflections

- Percent Open Questions (% OC)
  = OQ / (OQ + CQ)

- Reflection-to-Question Ratio (R:Q)
  = Total reflections/(CQ + OQ)

- Percent MI Adherent (% MiA)
  = MiA / (MiA + MiNa)

TRAINING STRATEGY FOR THE MITI

Give me a fruitful error any time, full of seeds, bursting with its own corrections. Pareto 1848-1923

Training coders to competency, as measured by interrater reliability and matching to a gold standard, usually requires a stepped learning process. We have found that coders do best beginning with fairly simple tasks, proceeding to more complex ones only when competence on the simpler tasks is solid. We recommend that coders begin by learning Level I tasks to an acceptable reliability standard prior to attempting Level II tasks. Only when acceptable standards for simultaneous I and II tasks have been accomplished should coders begin on Level III tasks. The self-review of MI text and video learning tools can be used at any time (perhaps as a prelude to beginning Level I tasks).

Behavior Count or Summary Score Thresholds	**Beginning Proficiency**	**Competency**
Global Clinician Ratings	Average of 3.5	Average of 4
Reflection to Question Ratio (R:Q)	1	2
Percent Open Questions (%OC)	50%	70%
Percent Complex Reflections (%CR)	40%	50%
Percent MI-Adherent (% MIA)	90%	100%

The use of pre-scored gold standard transcripts will assist in evaluating coder competency and areas for improvement. We have found that coders often have difficulty in one area or another, requiring a more intensive focus. Problem areas can be identified using standardized transcripts as a quiz for each level. More than one quiz per level is often needed. We have found that coders typically require 40 hours of training to reach interrater reliability using the MITI. In addition, regular (probably weekly) group coding sessions are optimal to insure drift does not occur. Clinical experience (i.e. being a clinician) has *not* predicted ease of training or eventual competence in our laboratory.

Level I competencies: parsing utterances, giving information and open/closed questions
Level II competencies: add reflections, MiA and MiNa
Level III competencies: add global ratings

Below are recommended proficiency and competency thresholds for clinicians, based on the MITI coding system. Please note that these thresholds are based on EXPERT OPINION, and currently lack normative or other validity data to support them. We are in the process of gathering normative data for the revised MITI now. Until such normative data is available, these thresholds should be used in conjunction with other data to arrive at an assessment of clinician competency and proficiency in using MI.

Motivational Interviewing Treatment Integrity Code (MITI)

Coding Sheet Revised June, 2007

Tape #_____ Coder:_____ Date:_____

Global Ratings

Evocation		1 2 3 4 5 Low High
Collaboration		1 2 3 4 5 Low High
Autonomy/ Support		1 2 3 4 5 Low High
Direction		1 2 3 4 5 Low High
Empathy		1 2 3 4 5 Low High

	Behavior	**Counts**	
Giving Information			
MI Adherent	**Asking permission, affirm, emphasize control, support.**		
MI Non-adherent	**Advise, confront, direct.**		
Question (subclassify)	**Closed Question**		
	Open Question		

Reflect (subclassify)	**Simple**		
	Complex		
	TOTAL REFLECTIONS:		

First sentence:_____

Last sentence:_____

List of MITI Codes

EVOCATION	(Global rating of evocation)
COLLABORATION	(Global rating of collaboration)
AUTONOMY/SUPPORT	(Global rating of Autonomy/Support)
DIRECTION	(Global rating of direction)
EMPATHY	(Global rating of empathy)
SPIRIT	(Global rating of MI Spirit; Average of Evocation, Collaboration, Autonomy/Support)
GI	(Giving Information)
MiA	(MI Adherent)
MiNa	(MI Non-adherent)
OQ	(Open Question)
CQ	(Closed Question)
Rs	(Reflection simple)
Rc	(Reflection complex)

Note: Coded transcripts of two MI interviews, taken from the Professional Training Series, are available to assist you in learning to use the MITI. For ease in learning, each interview is coded twice—once for global ratings and once for behavior counts—although in practice both tasks would usually be done simultaneously. These transcripts, along with the MITI manual itself, can be downloaded free of charge from

Appendix II Continued: BECCI

Behaviour Change Counselling Index (BECCI)

BECCI is an instrument designed for trainers to score practitioners' use of Behaviour Change Counselling in consultations (either real or simulated). To use BECCI, circle a number on the scale attached to each item to indicate the degree to which the patient/practitioner has carried out the action described.

Before using BECCI, please consult the accompanying manual for a detailed explanation of how to score the items. As a guide while using the instrument, each number on the scale indicates that the action was carried out:

A. Not at all
5) Minimally
6) To some extent
7) A good deal
8) A great extent

The Topic: _____

Item	Score
1. Practitioner invites the patient to talk about behaviour change **Not Applicable** ☐	**not at all** 0 1 2 3 4 **a great extent**
2. Practitioner demonstrates sensitivity to talking about other issues	**not at all** 0 1 2 3 4 **a great extent**
3. Practitioner encourages patient to talk about current behaviour or status quo	**not at all** 0 1 2 3 4 **a great extent**
4. Practitioner encourages patient to talk about change	**not at all** 0 1 2 3 4 **a great extent**
5. Practitioner asks questions to elicit how patient thinks and feels about the topic	**not at all** 0 1 2 3 4 **a great extent**
6. Practitioner uses empathic listening statements when the patient talks about the topic	**not at all** 0 1 2 3 4 **a great extent**
7. Practitioner uses summaries to bring together what the patient says about the topic	**not at all** 0 1 2 3 4 **a great extent**
8. Practitioner acknowledges challenges about behaviour change that the patient faces	**not at all** 0 1 2 3 4 **a great extent**
9. When practitioner provides information, it is sensitive to patient concerns and understanding **Not Applicable** ☐	**not at all** 0 1 2 3 4 **a great extent**
10. Practitioner actively conveys respect for patient choice about behaviour change	**not at all** 0 1 2 3 4 **a great extent**
11. Practitioner and patient *exchange* ideas about *how* the patient could change current behaviour *(if applicable)* **Not Applicable** ☐	**not at all** 0 1 2 3 4 **a great extent**

Practitioner BECCI Score: _____

Practitioner speaks for (approximately):-

More than half the time ☐ About half the time ☐ Less than half the time ☐

Appendix III: Participant Consent Forms and Information Sheets

King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON
University of London

Diabetes Research Group
Division of Diabetes & Nutritional Science
King's College London School of Medicine
King's College Hospital Campus
James Black Centre
London
SE5 9NU

D- 6 ID:
Researcher ID:
Date:

CONSENT FORM, version 2, REC No. 09/H0808/97

Title of Project: Diabetes 6 (D-6)

Please initial box

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree for my medical notes to be checked by the research team during the 2 years of the study ☐
4. I agree to take part in the main study ☐

Please delete the following items if you do not wish to do them:

5. I agree to a blood test for this research approximately 4 times ☐
6. I agree to be invited for further interviews and blood tests upto 5 years after the initial study has ended ☐
7. I understand that information held by the NHS and records maintained by The NHS Information Centre and the NHS Central Register may be used to help contact me and provide information about my health status. ☐
8. I agree for my sessions with the practice nurse to be audio recorded. ☐

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

D6 Consent Form V.2 27/07/2011

King's College Hospital NHS
NHS Foundation Trust

Division of Gene & Cell Based Therapy
King's College London School of Medicine
King's College Hospital Campus
James Black Centre
London
SE5 9NU

KING'S College LONDON
University of London

Participant information sheet (version 1) REC No. 9/H0808/97
The D- 6 (Diabetes-6) study:

We would like to invite you to take part in a NHS-funded research study. Your General Practitioner (GP) has informed you of the study because you have Type 2 diabetes and your diabetes control is not as good as it could be. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1 – purpose of the study
Many people with Type 2 diabetes have difficulty achieving recommended blood glucose levels. There may be many reasons for this but often the main reason is that having diabetes necessitates a change in lifestyle and these can be very difficult to achieve. Psychological treatments can help people explore barriers preventing them from getting better diabetes control but usually these treatments are offered by psychologists. We would like to find out if practice nurses can deliver this type of therapy to help their patients with diabetes. Your GP practice may be randomised to one or the other group. By random we mean that there is an equal chance that your GP will be selected into one of these groups. This is the best method for testing whether nurses who receive this special training can help patients achieve better control than those who do not receive this special treatment. Either way your practice nurse would be seeing you more frequently than usual to test whether the special nurse training is effective.

Do I have to take part?
It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?
One of our researchers will contact you to arrange a time to see you to explain the study in more detail. If you are happy to participate they will then perform a physical assessment, for example measure your height, weight and blood pressure. Following this you will receive a series of 12 diabetes appointments with your practice nurse over the course of the year.

What are the possible disadvantages or risks of taking part?
We do not foresee any disadvantages of participating in the study. However, if you were found to be badly depressed we would let you know and with your permission, we would offer to inform your GP for further treatment.

What are the possible advantages of taking part?
We cannot promise the study will help you but participating in this research would enable you to receive more time with your practice nurse for the treatment of your diabetes.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. We will also take measures to anonymise the data you give us. You will be given this information sheet and a signed consent form to keep.

Future research
We have funding for this research for 5 years in total but would like to continue collecting information about your diabetes for up to 10 years, so that we can see if any of this special nurse training is effective in the long-term. We would like to request your permission to continue to collect diabetes related data from your medical notes and to contact you after the present 2 year study is over.

Further information and contact details
If you would like further information about this study please contact:-

Jane Gregg	Dr Khalida Ismail	Dr Kirsty Winkley
Trial manager	Psychiatrist	Research Manager
020 7848 5669	020 7848 5131	020 7848 5664

King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON
University of London

Participant Information Sheet

Title of Study: Understanding the patients' experience of receiving integrated psychological and diabetes care

Invitation to the study

You are invited to take part in this study. Before you decide I would like to provide you with some information so that you can be clear what it will involve. Please take time to read the following information and discuss it with your family, friends, relatives or your GP if you wish. If you need any further information you are very welcome to contact Helen Graves, the researcher and PhD student who will carry out the interviews.

Purpose of the study

The study is sponsored by the NHS with the aim of finding out the views and experiences of patients with newly diagnosed type 2 diabetes who have participated in the Diabetes-6 Study, so that we can improve research in the future.

Why have I been chosen?

You are already participating in the Diabetes-6 Study and this study is an additional Diabetes-6 Study. We are contacting you because you have taken part in the main Diabetes-6 study and you also agreed to be contacted for future Diabetes-6 studies. The researcher Helen Graves will contact you by phone and ask you whether you want to take part in this new study. The aim is to approach about 40 patients.

Do I have to take part?

It is up to you to decide whether or not to participate in this study. If you agree the researcher will explain the study to you and this information sheet. You are free to withdraw from the study at any time and without giving a reason. Your future treatment will not be affected by your decision.

What will happen if I take part?

The researcher will contact you by phone after 2-3 days to establish that you want to participate in the study. If you agree they will then arrange a time with you to conduct the interview as part of your Diabetes 6 follow up appointment, which will be conducted at your GP practice.

Before the interview the researcher will make time to clarify any questions you may have. She will ask you to sign a consent form to say that you are happy to take part.

The interview may last for approximately 30 minutes to an hour. The interview will be audio taped, so that the researcher and/or a research colleague, employed in the same department can type out the information you provide. The tape recorder can be stopped at your request at any time, if you do not wish certain information to be recorded, and may be re-started with your agreement.

What might be the possible concerns taking part in this study?
Any effort will be made to arrange the interview with the researcher at a mutually convenient time. If for any reason you are unable to make the time arranged in advance, a new appointment can be made. If you provide information you do not wish to have recorded, the tape recorder can be stopped whenever you wish and restarted with your agreement.

What are the possible benefits of taking part in this study?
We hope that the information you provide will give us a better understanding of your experience of taking part in the Diabetes 6 study. In addition other patients with diabetes might be interested when the findings are published.

Will my participation in this study be kept confidential?
All information you provide during the interview with the researcher will be kept strictly confidential. Only the researcher will have access to the information you give. The external transcribing agency has a contract with the researchers department to treat all the information on the tape confidential. Information will not be given to the clinical team involved in your care without your specific consent. Your name will be replaced by a code only known to the researcher, so that you cannot be identified by any other person, including the external transcribing agency staff.

What will happen to the results of the study?
The information you provide together with the other patients will be analysed and written up as a report. The findings from the study will be published within one to two years after completion and a summary can be made available to you by posting it to you. You will not be identified in any of the future publications or reports we have to submit to the funding body (NIHR).

Who is funding the research?
The National Institute for Health Research (NIHR) is funding this study. The NIHR is the body which conducts research for the NHS.

Who has reviewed the study?
The research proposal has been reviewed by staff in the Department of Diabetes and Nutritional Sciences at King's College London and by the local Research Ethics Committee at Dulwich, London.

Contact for further information
If you have any questions or require further information about this study now or at any time during the study, you are very welcome to get in touch with the researcher Helen Graves on Tel. 0207 848 5780. If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at:

http://www.invo.org.uk/pdfs/guide_for_consumers.pdf or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.

Thank you very much for taking the time to read this information.

King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON
University of London

Research Ethics Ref: PNM/12/13-27

Participant Information Sheet

Title of Study: The Range and Diversity of Nurses' Personal Experiences and Views of the D6 Intervention

Invitation to the study
You are invited to take part in this study. Before you decide I would like to provide you with some information so that you can be clear what it will involve. Please take time to read the following information and discuss it with your family, friends or relatives is you wish. If you need any further information you are very welcome to contact Helen Graves, the researcher and PhD student who will carry out the interviews.

Purpose of the study
The study aims to find out the views and experiences of nurses who participated in the Diabetes 6 Study. The purpose of this is to improve research in the future.

Why have I been chosen?
You are already participating in the Diabetes-6 Study and the aim is to approach all nurses who took part.

Do I have to take part?
It is up to you to decide whether or not to participate in this study. If you agree the researcher will explain the study to you and this information sheet. You are free to withdraw from the study at any time during the interview and to withdraw your data at any point up until the data is analysed (01/10/2014), without giving any reason.

Should you feel uncomfortable asking the researcher to withdraw your data, you may do so via the researcher's supervisor, Dr. Khalida Ismail, whose contact details are provided at the bottom of this information sheet.

What will happen if I take part?
If you agree to participate the researcher will make time to clarify any questions you may have. She will ask you to sign a consent form to say that you are happy to take part. The interview may last for approximately 30 minutes to an hour. The interview will be audio taped, so that the researcher and/or a research colleague, employed in the same department can type out the information you provide. The tape recorder can be stopped at your request at any time, if you do not wish certain information to be recorded, and may be re-started with your agreement.

What might be the possible concerns taking part in this study?
Any effort will be made to arrange the interview with the researcher at a mutually convenient time. If for any reason you are unable to make the time arranged in

advance, a new appointment can be made. If you provide information you do not wish to have recorded, the tape recorder can be stopped whenever you wish and restarted with your agreement.

What are the possible benefits of taking part in this study?
We hope that the information you provide will give us a better understanding of your experience of taking part in the Diabetes 6 study. In addition other health professionals might be interested when the findings are published.

Will my participation in this study be kept confidential?
All information you provide during the interview with the researcher will be kept strictly confidential. Only the researcher will have access to the information you give. The external transcribing agency has a contract with the researchers department to treat all the information on the tape confidential. Your name will be replaced by a code only known to the researcher, so that you cannot be identified by any other person, including the external transcribing agency staff.

What will happen to the results of the study?
The information you provide together with the other nurses will be analysed and written up as a report. The findings from the study will be published within one to two years after completion and a summary can be made available to you by posting it to you. You will not be identified in any of the future publications or reports we have to submit to the funding body (NIHR).

Who is funding the research?
The National Institute for Health Research (NIHR) is funding this study. The NIHR is the body which conducts research for the NHS.

Who has reviewed the study?
The research proposal has been reviewed by staff in the Department of Diabetes and Nutritional Sciences at King's College London and the study has been approved by King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee.

Contact for further information
If you have any questions or require further information about this study now or at any time during the study, you are very welcome to get in touch with the researcher Helen Graves on Tel. 0207 848 5780. If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at: http://www.invo.org.uk/pdfs/guide_for_consumers.pdf or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.

If this study has harmed you in any way, you can contact King's College London using the details below for further advice and information.

Prof. Khalida Ismail
Department of Psychological Medicine
Weston Education Centre
King's College London
10 Cutcombe Road

SE5 9RJ
Tel: 0207 848 5131
E-mail: khalida.2.ismail@kcl.ac.uk

Thank you very much for taking the time to read this information

King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON
University of London

Consent Form

Title of Project: Understanding the patients' experiences of receiving integrated psychological and diabetes care

Name of Researcher: Helen Graves

Please initial box

1. I confirm that I have read and understand the Information Sheet for the above study and that I have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. My withdrawal will not affect my future care. ☐
3. I agree to take part in the study. ☐
4. I agree to be recorded during the interview. ☐

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Researcher	*Date*	*Signature*

(One copy for participant to keep, one to be kept by Researcher)

King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON
University of London

Diabetes Research Group

Division of Diabetes & Nutritional Science
King's College London School of Medicine
King's College Hospital Campus
James Black Centre

Date:

CONSENT FORM
Research Ethics Ref: PNM/12/13-27

Title of Project: *The Range and Diversity of Nurses' Personal Experiences and Views of the D6 Intervention*

Please initial box

1. I confirm that I have had the opportunity to consider my participation in the study and to ask any questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time during the interview and I am free to withdraw my data at any point up until the final report is written (01/10/2014), without giving any reason. ☐
3. I agree to take part in the above study. ☐
4. I agree for this interview to be audio recorded. ☐
5. I consent to the processing of my personal information for the purposes explained to me I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of person taking consent	Date	Signature

Appendix IV: Interview Schedules

D6 Patient Exit Interview Schedule

I would like to talk to you about your experience of taking part in the D6 study. The questions I ask will cover three key areas: the timings of your appointments with the nurse; any problems you may have encountered in taking part and your views about the treatment you received. At the end I would also welcome any additional information which I may have left out but which you feel is relevant about your experience of taking part.

Before we begin the interview, I must say that everything we talk about today will remain completely confidential. In order for me to listen back to our conversation later on however, I need your consent for me to record the conversation. Could you please confirm to me now that you are happy for me to do this?
If you provide any information which you do not wish to be recorded, the tape recorder can be stopped at any time and restarted at your request.

Timetable

First of all I would like to ask you about the timing of the extra appointments you had with [name of nurse] at [name of GP surgery].

- What are your views about the number of appointments you had with [nurse name]?
- What are your views about the length of the appointments?
- Now that the extra appointments with [nurse name] have come to an end, can you tell me what you think about seeing her less frequently again?

Barriers to Attending

- How did you find the first appointment with the researcher, the one before you started seeing the nurse?
- Could you tell me about any difficulties that you had attending the appointments with [nurse name]?

    - What would have made it easier to attend?

- What did you think about the way [nurse name] talked to you during the appointments?
    - Her style of talking?
- How do you think your relationship with [nurse name] has changed, if at all?

Treatment

- What are your views about the issues that you discussed with the nurse during the appointments?
    - Were there other issues you would rather have discussed?
    - If so, which ones?
- Can you tell me about any changes you've made to the way you manage your diabetes as a result of taking part in the research?
- Can you tell me about any changes in the way you feel about your diabetes as a result of taking part?
- Half the nurses taking part in D6 had special training in psychological skills, which were designed to help motivate people to manage their diabetes more effectively. Your nurse, [nurse name], **did/did not** have this special training. What are your views about this?
- Aside from the D6 study, what are your views about this kind of research in general?
- What are your views about using psychological therapies to help people manage their diabetes?
- How do you think we could have improved the treatment?

Final Comments

- Is there anything else at all you would like to say that we haven't covered already?

D6 Nurse Interview Schedule (Intervention)

I would like to talk to you about your experience of taking part in the D6 study. The questions I ask will cover 5 key areas: the D6 training; the intervention itself; the support you received during D6; any difficulties you encountered taking part and your opinions about research in general. At the end I would also welcome any additional information which I may have left out but which you feel is relevant about your experience of taking part.
If you provide any information which you do not wish to be recorded, the tape recorder can be stopped at any time and restarted at your request.

Training

You were allocated to the intervention arm of the trial, which meant that you attended King's for training in the D6 skills.

- How did you feel about the timing of the training sessions?
    - Frequency
    - Length
- Can you tell me about any problems you experienced with the training?
    - What would have made it easier for you?
- Can you tell me any ways in which you think the training could have been improved?

Support

- What are your views about the supervision received throughout the study?
- What are your views about the support you received from the research team in general?
- How did other members of staff at your practice feel about you taking part in the study?
    - Were they supportive/not supportive? How so?
    - What would have made it easier for you to participate?

D6 Intervention

- How did you feel about being randomised to the intervention arm of the study?

- How did you find the actual sessions with patients?
    - How did you find the length of the sessions?
- What are your feelings about the admin time involved in the study?
- What are your views about D6 as a potential training for other practice nurses?

Competency and Self Efficacy

- How confident did you feel about delivering the intervention?
- How confident did you feel about managing the caseload?

Patients

- Can you tell me about any difficulties you experienced in getting patients to attend the sessions?
    - Did you book the patients in yourself or did a researcher or receptionist do this for you?
- Thinking about the patients that did attend, how do you think they feel about seeing you less often again now that the extra sessions have come to an end?
- What were the challenges that you faced in using D6 skills with these patients?

Values about Psychological Research

- What are your feelings about the value of psychological interventions in general?
- How has participating in D6 affected your feelings about taking part in other research studies in the future?

Final Comments

- Finally, can you tell me about any ways in which you think we could have improved the research?
- Is there anything else you would like to say about the research that we haven't covered already?

D6 Nurse Interview Schedule (Control)

I would like to talk to you about your experience of taking part in the D6 study. The questions I ask will cover 5 key areas: training; the support you received during D6; the appointments with patients; any difficulties you encountered in taking part and your opinions about research in general. At the end I would also welcome any additional information which I may have left out but which you feel is relevant about your experience of taking part.
If you provide any information which you do not wish to be recorded, the tape recorder can be stopped at any time and restarted at your request.

Training

You were allocated to the control arm of the trial, which meant that you did not attend King's for training in the D6 skills.

- What were your views about being randomised to the control arm of the trial?
- Have you had any previous training in psychological therapies?

Supervision

- What are your views about the supervision you received throughout the study?
- What are your views about the support you received from the research team in general?
- How did other members of staff at your practice feel about you taking part in the study?
    - Were they supportive/not supportive? How so?
    - What would have made it easier for you to participate?

D6 Intervention

- How did you find the actual sessions with patients?
    - How did you find the length of the sessions?
- What are your views about the admin time involved in the study?
- What are your views about D6 as a potential training for other practice nurses?

Self Awareness

- How confident did you feel about delivering the intervention?
- How confident did you feel about managing the caseload?

Patients

- Can you tell me about any difficulties you experienced in getting patients to attend the sessions?
    - Did you book the patients in yourself or did a researcher or receptionist do this for you?
- Thinking about the patients that did attend, how do you think they feel about seeing you less often again now that the extra sessions have come to an end?
- What were the challenges that you faced in seeing these patients?

Values about Psychological Research

- What are your views about the value of psychological interventions to improve outcomes in diabetes?
- How has participating in D6 affected your views about taking part in other research studies in the future?

Final Comments

Is there anything else at all you would like to say that we have not already covered?

Appendix V: D6 Training Manual

The Diabetes-6 (D-6) Study

A psychology skills handbook for primary care nurses supporting patients with Type 2 Diabetes

D-6 Handbook V2

Contents

	Foreword
A	**D-6 Background**
1	**Skill 1: Active listening (MI)**
2	**Skill 2: Managing resistance (MI)**
3	**Skill 3: Directing change (MI)**
4	**Skill 4: Supporting self efficacy (MI + CBT)**
5	**Skill 5: Addressing health beliefs (CBT)**
6	**Skill 6: Shaping behaviour (CBT)**
B	**Integrating the skills**
C	**Trouble shooting**
D	**Identifying mental health problems**
E	**Longer case examples**
F	**Useful tools appendix**

D-6 Handbook V2

Foreword

This handbook is written for the NIHR funded D-6 study.

It is intended as a training resource and reference handbook for diabetes professionals working with Type 2 Diabetes patients with persistent suboptimal glucose control.

The handbook covers six core psychological skills for diabetes professionals. It draws on Motivational Interviewing and Cognitive Behavioural Therapy, which are introduced in the first section. Each section includes a rationale for why the skill is useful, a description of specific techniques and how to administer them. Each section also considers potential problems which may arise for the clinician in using each skill.

The following sections of the handbook cover how to integrate these skills depending on the patient's needs, a trouble shooting section which considers possible reasons for no change in the patient's behaviour and longer case examples. Examples of dialogue between diabetes patients and clinicians are used throughout the handbook to illustrate the skills in action.

The final sections of the handbook consider how to assess for common mental health problems and provide a list of local community resources to support lifestyle changes. A useful tools section will also be found at the end of the handbook, with handouts for patients and clinicians including visual aids, questionnaires and prompts for discussion.

Written by **Dr Nicole de Zoysa, Clinical Psychologist**

Thanks to Melanie Rimes for the illustrations

Intellectual property of King's College, London. Do not reproduce without permission. V2.

Section A:
D-6 Background

D-6 Handbook V2

D-6 Background

Why do we need to consider psychology in diabetes?

In the 21st century, the management of long-term conditions is an increasing priority for the NHS. With chronic disease management comes a greater responsibility for the *patient* in managing their own health. For some patients, taking on this role is much harder than for others. The patients who struggle continue to mistreat themselves or fail to make lifestyle adjustments, despite the prospect of disease progression. In Type 2 diabetes, 60% of patients are failing to achieve target (Massi-Benedetti, 2006) despite access to sophisticated technology and health education. This is frustrating for everyone concerned.

Both Motivational Interviewing and Cognitive Behaviour Therapy are psychological approaches that tackle the area of behaviour change. They have been shown to improve outcomes for diabetes patients and reduce HbA1c (Ismail, Winkley, Rabe-Hesketh, 2004). These approaches suggest that how we *talk* to a patient, the *questions* we ask and the *attitude* we bring to our consultation can significantly affect outcome. The aim of the D-6 study is to train practice nurses in some of these techniques to support those patients who are struggling.

Introduction to Motivational Interviewing (MI)

What is Motivational Interviewing?
Motivational interviewing is a consultation style designed to strengthen a patient's commitment towards change. MI is both *person centred* (understanding and affirming the patient's point of view) and *directive* (guiding them towards behaviour change).

The key tasks in MI can be summarised as follows:

EE Expressing Empathy
RR Rolling with Resistance
AA Avoiding Arguments
SS Supporting Self efficacy
DD Developing Discrepancy

A useful acronym for remembering these is DEARS. These areas will be covered in detail in the subsequent chapters.

The development of MI
MI was originally developed from the field of alcohol misuse. Bob Miller, an American Psychologist, and his colleagues became interested in finding cost effective treatments for people with alcohol problems. They noticed that some therapists had more success with their clients than others, even when the clients had been randomly assigned. The researchers started to look at the transcripts from these sessions and investigated what factors predicted better outcomes. Surprisingly, they found that

D-6 Handbook V2

resistance was a by-product of the *interaction* between the therapist and the client. This challenged the notion that resistance was exclusively to do with the client.

Specifically, they found that when counsellors gave confrontational responses (even with good intentions), this would elicit increased defensiveness (i.e. resistance or denial) from the client. Therapists who expressed high empathy had patients with better outcomes. Furthermore, if therapists changed their style from a confrontational to a client-centred approach, client defensiveness reduced. Looking at transcripts of client responses, they found that client defensiveness could predict lack of behaviour change. This body of research suggested that the degree of resistance or motivation displayed by a client could be modified by the therapist's behaviour.

For more information regarding the theories associated with MI, see Appendix.

The 'spirit' of MI

MI is more than just a collection of techniques. The 'spirit' of MI is about adopting a certain attitude or mindset that will promote behaviour change. The underlying principles of MI can be summarised as follows:

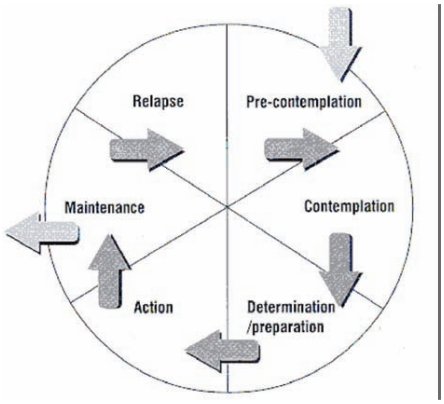
- *Collaborative* – a joint decision making process, with both parties having an equal share of the power. Only the patient can enact a behaviour change – their viewpoint needs to be respected and utilised.
- *Evocative* – the art of MI is to connect healthy behaviour with what patients care about or value. MI seeks to draw out from the patient their reasons, values, resources and beliefs about change. Consequently, patients provide their own arguments for change.
- *Honouring patient autonomy* – an acceptance that people are allowed to make their own choices about their health. Ironically, acknowledging a person's right *not* to change can sometimes give space for change to occur.

When you are in the flow with MI, consultations feel different; you meet patients where they are; you demonstrate you understand – the sense of struggle is abated. When patient defensiveness has gone down, you then have room to manoeuvre to guide them towards better self care. Rollnick (2008) reminds us that MI is "about guiding more than directing; dancing rather than wrestling; listening at least as much as telling" (p.6). Consequently, this handbook has been divided into 'what to do' sections i.e. technique and 'how to do it' sections, describing the style or spirit.

D-6 Handbook V2

The process of change

The MI approach draws upon Prochaska & DiClemente's (1983) Stages of Change (SoC) model. This model suggests that change is not an 'all or nothing' concept but that people pass through different stages (including contemplating a change and making preparations), moving backwards and forwards, before reaching a maintenance stage (see diagram below).



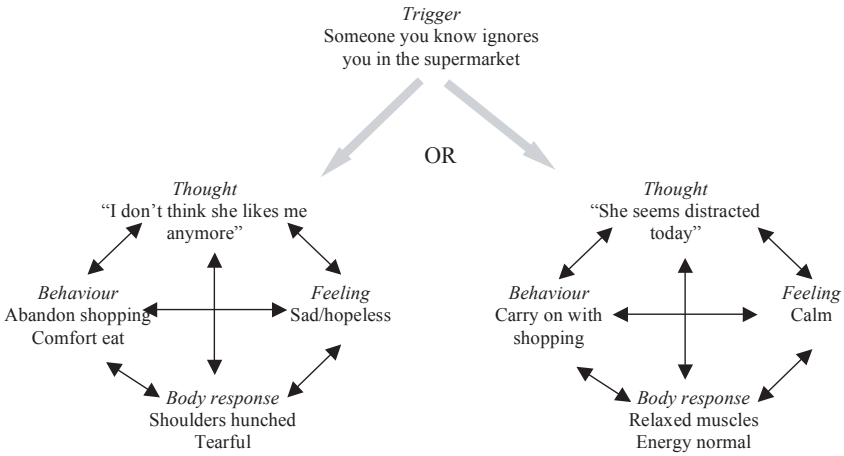
The skill of MI is to meet your patient where they are on the cycle of change and to adapt your consultation accordingly. For example, if you proceed with goal setting with a patient who is still weighing up the pros and cons of doing exercise, you may notice an increase in resistance. This is because the clinician is in 'action' and the patient is in 'contemplation'. According to this model, resistance occurs when the patient and clinician are at different stages on the change cycle. (see Appendix for more information regarding the Stages of Change model).

The majority of patients with poorly controlled diabetes are not ready to move into action to improve self-care when they first present. The resistance may not always be easy to recognise. Patients may avoid expressing their irritation, anger or rebellion to you directly. However, the resistance becomes obvious when they come back the next month with their sugar levels unchanged.

D-6 Handbook V2

Introduction to Cognitive Behavioural Therapy (CBT)

What is Cognitive Behavioural Therapy?
Cognitive Behavioural Therapy was first developed as a treatment for depression by Beck (1967). It arose from the realisation that how a patient reacted emotionally depends on how they *interpret* events. Consequently, CBT rests upon the idea that cognitions (e.g. thoughts, beliefs, attitudes) influence our emotional, physical and behavioural responses. Consider these two examples:



What Beck discovered is that these thoughts can appear so quickly and so fleetingly that the person may not be consciously aware of them. For example, if you ask someone to give a speech in front of a room full of people, they may notice that their heart rate increases and that they start to perspire. However, they may not be aware of any thoughts at the time. By asking the person specific questions, we can find uncover the 'hidden' interpretation of the event i.e "I might mess it up", "my face will go red" or "my boss will judge me negatively". These sorts of thoughts are called Negative Automatic Thoughts (NATs) and the role of therapy is to help the patient become aware of them.

CBT works on the assumption that when patients are suffering from an emotional disorder e.g. depression or anxiety, they may hold unrealistic or unhelpful beliefs which are contributing to the problem. Common unhelpful ways of thinking include:

- Catastrophising - focussing on the worst case scenario
- Personalising - assuming anything that goes wrong is my fault
- Black and white thinking - viewing a situation from extreme positions

D-6 Handbook V2

The aim of therapy is to help patients identify these automatic thoughts, using certain questions e.g. what went through your mind just then?; what does that say about you as a person?, what conclusions do you draw from this event? Patients may be asked to keep thought records to make a note of habitual ways of responding. Once the thought has been identified, the therapist will support the patient in exploring alternative viewpoints. This helps the patient to realise that their experience (e.g. sadness) is being coloured by their thoughts and that there may be an alternative or more helpful way of viewing the situation (cognitive restructuring). The behavioural part of CBT involves behavioural experiments. This involves testing out a patient's predictions by trying out new behaviours and observing the results objectively. Goal setting and problem solving are other behavioural techniques used in CBT.

The aim of this course is not to turn you into a CBT therapist, but to understand the theory linking thoughts to behaviours/feelings and to provide a few techniques e.g downward arrow (see Chapter 5) to enhance your consultations. These skills may be particularly helpful when managing patients who have co-morbid depression or anxiety.

Working with health beliefs

Even if a person is not feeling clinically depressed or anxious, the way they think about their illness will influence how they manage it. There are several theories from health psychology which highlight the role of beliefs in health behaviours e.g Leventhal's self regulatory model (2001) and Ajzen's theory of planned behaviour (see Appendix). These theories hold that patients will form certain ideas about their illness, the value of self care behaviours, the success of past efforts to manage it and other people's perceptions. For example, if a patient believes their diabetes is temporary, they may not see the need for medication. Seen in this way, seemingly "irrational" behaviour can start to make more sense. The D-6 model assumes that there is always a rationale for a patient's behaviour (even if it isn't immediately obvious). By asking the right sorts of questions, we can use our consultations more effectively to target the unhelpful thoughts or beliefs that are maintaining poor self care. As a result, you will be better equipped to deal with some of the psychological barriers to glycaemic control. D-6 is not about offering psychotherapy but providing *psychologically enhanced* consultations around diabetes.

D-6 Handbook V2

Psychological skills in a medical setting

A normal question to ask at this stage is how different the D6 skills might be to what you do already. You have a level of expertise to fall back upon in terms of your nursing and diabetes experience and no doubt have had to handle patients of varying complexity. As you read this handbook, you will probably notice skills that you already use in day-to-day practice. Indeed, the D6 skills build upon already established good nursing practice (e.g. active listening). However, there will be some areas that feel very different to routine practice and that highlight the challenges of adopting a psychological model. It is best to be prepared for this culture shift.

Who's the expert?
MI encourages you to view the patient as the 'expert'. This is very different from the patient seeking 'expert' advice and treatment from the clinician. In this situation the patient is passive and knows less than the healthcare provider. In behaviour change work, however, the patient becomes 'active'. You may suggest exercise/dietary changes, but it is the patient who knows best how to integrate this into their lives - they know when they go shopping, when they feel most tired, who can help with childcare, what exercise they prefer etc. In order to liberate that knowledge, we need to suppress our own 'righting reflex' i.e. telling them what's best!

One way to view this is that the patient becomes the Consultant or Specialist about themselves. This means you are consulting *them* about how to change their behaviour, rather than the other way round. This can be particularly difficult for healthcare professionals who are drawn to this work because they actively want to help others. A sign that we are doing our job well is that we have informed, educated, problem-solved, prescribed and ultimately fixed our patients. Although helpful in a lot of situations, when it comes to long-term *lifestyle* changes, the patient needs to take over the reins of responsibility. Letting go of this can feel unsettling at first, especially when we are well versed in problem-solving on the patient's behalf.

How do I know I'm doing anything useful?
The D6 intervention will encourage you to expand your idea of clinical 'work'. For instance, there is more emphasis on 'listening' as a clinical tool. This is where we can become unstuck. Work is often conceptualised as writing a prescription, taking someone's blood pressure or giving health advice (i.e. practical directive action). A good outcome will involve some sort of goal-setting or plan. Without this it may feel like we haven't done our job very well.

However, this intervention will also involve listening, reflecting and tolerating some ambivalence (i.e. the patient is in two minds). Through listening we give space for the patient to explore their ambivalence, show that we are interested in them and obtain vital information to guide our consultation. We will learn to respond in ways that fuel motivation. In this way, our 'talk' is also part of our therapeutic armoury – potentially as powerful as the drugs we administer.

For D-6, 'work' about moving a patient along in their thinking. The goal for a session is to increase the amount of pro-change statements made by the patient (i.e. moving them through the stages of change). This is still 'work' even if it's not accompanied

D-6 Handbook V2

by a more practical action. In fact, by focussing prematurely on action we may induce further resistance from the patient. Sometimes *not* doing something can be the more skilful response.

The ticking clock
It is common to worry that by asking patients what they think and how they you're your consultation time will overrun. Remember that you're not being asked to do 'therapy' with a patient. Your questions will focus upon diabetes related concerns and with practice you will become more skilled at steering the conversation in the relevant direction. In addition, it is not your job to 'fix' all the problems you unearth in one session. Sometimes, this means ending a session with a sense that things are still 'undone'. This is to be expected for a long-term intervention such as D-6.

It is also common to *overestimate* the amount of time that has passed when someone else is talking and to *underestimate* the amount of time that has passed when we are talking. Research suggests that even one to two minutes of real listening (without a hidden agenda) can make a significant difference to the outcome of your consultation. Yet two minutes can feel like an eternity to a silent healthcare professional!

Worry about time can actually provide a very real distraction. If we approach a task thinking "I've only got 5 minutes" the whole project may take much longer because we are distracted by the urgency of time. However, if we approach a task as if it will take 15 minutes (i.e. take the time pressure off) we can be more fully present to the task at hand and therefore respond more skilfully. Paradoxically, this often has the effect of achieving the same outcome in less time i.e. of speeding things up.

These are some comments made by Swedish primary care nurses[1] who underwent some training in Motivational Interviewing.

> *'After 25 years, old habits die hard' 'the difficult part is the re-learning, as the method in itself really isn't that difficult. It's important to be really focussed because it's easy to revert to what is habitual'*
>
> *'We didn't listen much before …instead we used to bombard people with advice, which was something we had been taught to do'*
>
> *"The more you understand the principles* [of MI]*, the more you really begin to appreciate motivational interviewing"*

[1] Reported by Soderlund et al 2008

D-6 Handbook V2

References

Massi-Benedetti M: Changing targets in the treatment of type 2 diabetes. Current Medical Research Opinion 2006, 22 Suppl 2:S5-13.

Ismail K, Winkley K, Rabe-Hesketh S. Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. Lancet 2004; 363: 1589-97

Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. Journal of Consulting and Clinical Psychology 1983, 51(3) 390-5

Soderlund LL, Nilsen P, Kristensson M Learning motivational interviewing: Exploring primary health care nurses' training and counselling experiences. Health Education Journal 2008; 67 (2) 102-109

Beck, A.T. (1967) Depression: Causes and treatment. Philadelphia. University of Pennsylvania press

Rollnick, S. Miller WR, Butler, CC (2008) Motivational Interviewing in Health Care: Helping Patients Change Behavior, Guilford Press

Chapter 1:
Active Listening

D-6 Handbook V2

Skill 1: Active Listening

Why is Active Listening important?

Listening can appear a deceptively simple task. In fact, it is a very complex skill and forms the foundation for all therapeutic interventions. Poor listening can result in missing vital information, the patient feeling misunderstood and disengaged from the consultation. Listening is often perceived as a passive skill, but we will go on to show that good listening involves being highly active and is more than asking questions and remaining silent during the answer.

Good listening demonstrates to the patient that you are interested in what they are saying and are able to express empathy with their difficulties. Both these messages are the building blocks from which a therapeutic rapport is formed. Without this rapport, patients may not feel able to be honest about their struggles and hopes (i.e. their ambivalence) and to try out new behaviours. This is particularly relevant to diabetes patients, whose 'unheard' stories may be driving poor glycaemic control.

Active listening is the cornerstone of all motivational interviewing. However, there are situations when it is particularly relevant.

- At the start of a consultation, when the focus is on understanding what has brought the patient into the room
- When the interaction between you and the patient feels particularly stuck or resistant
- When the patient is highly emotional e.g. tearful, angry or anxious

Some guidance on 'what to do' and 'how to do it' with regard to Active Listening are presented below.

D-6 Handbook V2

Active listening – WHAT to do

The following acronym summarises four techniques which can be used to promote active listening: OARS.

- **O**pen questions
- **A**ffirmations
- **R**eflections
- **S**ummaries

As oars are used to steer a rowing boat, these metaphorical oars can help steer the consultation in a pro-change direction. How you use them, in terms of attitude and body language, will also have a significant bearing on this.

Open Questions

Most consultations will involve a mixture of closed and open questions. The use of open questions is an important tool in behaviour change work. Open questions allow patients to elaborate on their answers. The more patients talk about their reasons for changing or not changing, the more pointers we receive about how to direct and pace the consultation. Closed questions can be counter productive in behaviour change because they can produce "yes/no" answers which tell us very little about any motivation to change.

Open questions also shift the balance of power towards the patient. It is easy to fall into the 'question/answer' trap which places the onus on you to think of the next question for the passive patient. It maintains the status quo (i.e. that you must do all the work in the consultation) and moves away from a collaborative approach. A string of closed questions can also provoke resistance in a patient. It contributes to a sense of being 'processed' rather than understood. Consider these two examples:

D-6 Handbook V2

Example 1

C: Do you know your latest HbA1c?
P: No
C: It's 10.2%
C: Do you know what that means?
P: Not sure
C: It's not a good sign. The glucose levels in your body are too high, putting you at risk for a number of complications.
C: Does that concern you?
P: I suppose that's not good
C: Well, we need to do something about that then. Let's start by looking at your diet …

Example 2

C: Do you know your latest HbA1c?
P: No
C: It's 10.2%
C: What does that mean to you?
P: Maybe that's why I've been feeling so tired and thirsty?
C: So you've noticed having less energy and needing to drink more. How does that impact on your life?
P: Well it's a hassle when I go to new places with the kids – I'm always worrying where the nearest loo is.
C: Maybe we could think about ways to improve this for you – what do you think?
P: I'm prepared to listen to what you've got to say …

In the second example the clinician has revealed some of the reasons for change and the patient's readiness to take on new information. In the first example, we have little indication of what the patient thinks about their HbA1c, what difficulties it's causing them, what might be the driver for change, and whether they are at all ready to think about change. The patient has become passive in the whole process, not volunteering any more information than the bare minimum.

An open question encourages more than a one word response. They can start with:

- *What / Why / How*
- *Tell me more about …*
- *Say some more about …*
- *That's interesting - please expand on that …*

Closed questions are more likely to start with:

- *Can you …*
- *Do you …*
- *Have you …*
- *How many …*
- *When …*
- *Where …*

D-6 Handbook V2

Example 3

CLOSED *Do you have any worries about your diabetes?*
OPEN *What worries you the most about your diabetes?*

CLOSED *Does your wife know about your hypos?*
OPEN *How does your wife feel about your hypos?*

CLOSED *Have you tried Weight Watchers before?*
OPEN *What are your thoughts about the Weight Watchers programme?*

The patient has indicated they aren't taking all their injections
CLOSED *How many injections do you miss a week?*
OPEN *What makes it harder for you to take your insulin sometimes?*

Closed questions can shut down the patient prematurely. Therefore, it gives you less to work with and the responsibility for change is back in your court. Open questions allow the patient to take some control with the direction of the answer. It also signals that you are interested in their perspective.

Affirmations

Affirmations are statements which demonstrate support for the patient. They may reflect positive aspects of a patient's behaviour, highlight their attributes or validate their efforts. Affirmations are important for a number of reasons. They colour the emotional tone of the consultation – creating a positive, hopeful and constructive atmosphere. It is important to consider what feelings a patient will be left with once they have left the room. Will they feel uplifted or downcast? Long after the words have faded, it is the emotional tone of a consultation that will stay with the patient and influence their subsequent behaviour outside the clinic room.

Affirmations can encourage positive self talk in the patient. Patients who are depressed have a tendency to focus upon the negative aspects of themselves or the world and discount the positive (see chapter 5). By providing affirmations, you are highlighting their capabilities and strengths e.g. resilience, problem-solving, or flexibility. You also demonstrate that their efforts are worth acknowledging. This provides an opportunity for patients to hear new 'stories' about themselves, build their confidence and their sense of hopefulness.

Consider these examples:

P: I know I should have done better
C: Your health is important to you

C: You sound like someone who can multitask very well - how might that skill apply to your diabetes?

D-6 Handbook V2

[20 minutes late]
C: I'm sorry you've had so many obstacles to get here, but I'm impressed with your persistence to still attend the appt

---

P: I missed a few doses – not very good – I'm falling back into old habits.
C: Can we slow things down?
P: OK.
C: How many were you missing, in average week, when we first met?
P: About 4 or 5
C: And how many now?
P: 2
C: That's an improvement of 50% - well done. What do you think about that?
P: Well I suppose I didn't see it like that
C: Tell me how you managed that?

P: I can't get it down. I eat sensibly, I always take my background, I just hate my mealtime injections.
C: You really take your diabetes seriously and put a lot of work into managing it –you are very committed to this

---

In the above examples, it would have been easy to get dragged down by the patient's pessimism and immediately focus on what could have been improved. This means we are giving attention to the wrong behaviour i.e. what they haven't done, not what they have. This can fuel their pessimism and hopelessness.

Reflections

Reflections demonstrate to the patient that you are listening and have understood what they have said. The key to reflective listening is to think in terms of hypothesis testing. The patient has told you something and you form a hypothesis (best guess) about what you think the patient means. Then you reflect your hypothesis back to them. One way to approach this is to *imagine* saying the words "Do you mean ….?" In practice, you leave the "do you mean" part out and just present the patient with the second part i.e. the reflective statement.

There are different levels of reflection:

Simple reflections
This is a basic acknowledgement of what a patient has said. It involves either repeating back to them what they have said or rephrasing it by changing a few of the words. It can be useful at the start of a consultation or when the situation is getting heated.

Examples:

D-6 Handbook V2

P: When I try and lose weight, I always end up piling on the pounds again
C: You've tried losing weight in the past, but it's been hard to maintain

P: I always take my tablets. There isn't a day that goes past that I miss one.
C: You take your tablets every single day, no matte what

P: I feel really disappointed in myself that I couldn't come here and say I've achieved more this week
C: You feel disappointed.

Complex reflections
Complex reflections add something additional to what the patient has said. This may mean drawing out what has been implied but not said explicitly (e.g. an emotion) or creating a shift in emphasis. The latter allows you to use reflective statements strategically to emphasise ambivalence, roll with resistance or elicit change talk. There will be more on these complex reflections in further chapters. The following are types of complex reflection:

Selective attention / Positive reframing (see Chapter 2 and 4)
Overshooting/undershooting – amplified reflections (see Chapter 3)
Double sided reflections (see Chapter 3)
Reflecting emotional tone (see Chapter 2)

Complex reflections are more appropriate when the clinician has got to know the patient, formed a rapport and has a better sense of their perspective and feelings. Different types of complex reflection will be introduced in subsequent chapters.

Summaries

A summary is an expanded group of reflective statements. Summaries provide a way to assess where you have got to in a conversation. They can provide a pause, time to reflect and digest what has been said. This can be particularly helpful if the pace of the dialogue is starting to feel frenzied. A summary may provide a turning point, after which you can change direction in a consultation. Summaries are often used to mark significant landmarks in the consultation e.g. the start, midway and the end.

Example:

P: I find that diabetes consumes all my life, because all I'm thinking is, what can I eat? What can I eat? What can I do? What can't I do? And I don't want to become obsessive about it. But everything is geared up towards your next blood test. Everything is geared up towards your next injection and I find it's very oppressive ...It's the vastness of it, it's the ... thinking you're doing the right things and having hypos. Thinking you're doing the right things and your blood sugar is way off the scale, you know! Not even being able to pin point anything specific to say ... oh! This is what triggered that, or that's what triggered ... you know! You think you got it there, you think you've got it under control and the next thing you know ... it's frustrating as I say. I mean I

D-6 Handbook V2

got a booklet erm … to record my testing in, and on the front of it, there is a picture of a man playing a trombone and it says "diabetes does not have to control your life" …huh I wish!

C: *So let me see if I've got this right Sarah. There are several things you were saying there. That diabetes has an impact on so many areas of your life like the testing, what you're eating, managing hypos - that it feels like there is a possibility of getting obsessed with it, because there are so many things you could be monitoring all the time. The other thing I'm hearing is that no matter what you do, you're not even sure if it's even having the right impact on your diabetes and that's frustrating.*

P: *Yeah exactly*

C: *Where do you think you're at now with your diabetes management?*

In the above example, the patient is feeling extremely frustrated. The clinician uses the summary as an opportunity to reflect back the patients concerns and create a pause in the consultation. Notice how the clinician does not try to problem solve or challenge what the patient is saying. The summary is used to establish rapport and reduce patient defensiveness.

Intellectual property of King's College, London. Do not reproduce without permission. V2.

D-6 Handbook V2

Active listening – HOW to do it

Open Questions
The attitude behind open questions is one of curiosity, of showing a genuine interest as to how your patient views their diabetes. Remember that the patient has the answers if we hold out long enough to hear them. Try to hold back from making any assumptions at this point or thinking of solutions. The approach is exploratory. Keeping this is mind will enable you to really listen to what the patient is telling you. Having a hidden agenda is distracting and will diminish the quality of your listening.

Affirmations
Affirmations may feel difficult at first. The key is to constantly be on the look out for the 'green shoots' (see more about this in Hotspots). Try and keep your praise *specific* and *authentic*. Useful questions to ask yourself are:

- What exactly are you congratulating them for and why is it worth commenting on?
- What effort will they have had to put in to achieve this?

Specific praise tends to carry more weight than vague praise. Consider these examples:

C1: Well done for losing 4 pounds – that's brilliant!

C2: I'm really impressed that you stuck with your diet over Christmas. It must have taken a lot of commitment to avoid temptation at that time of the year.

C1: It's really good that you've taken those injections over the past week.

C2: You've shown courage in facing your fears about injections. There may have been times that you felt like not going through with it, but you found a way to get beyond that. How did you manage it?

C1: Congratulations on making it to the gym this week!

C2: It's fantastic news that you've signed up to the gym. It's been something you've been putting off for a while, but this week you decided to bite the bullet and make your health a priority. How did that feel?

In the C2 examples, the clinician is not only giving praise but communicating an understanding of the struggles/sacrifices that needed to be overcome. This sort of affirmation is longer but follows the principle (from behavioural psychology) of giving more attention to the constructive behaviours. The C2 examples also lend themselves more readily to further elaboration from the patient e.g. How did you manage that? How did that feel?

Following from this, it can be useful to reflect upon how much of your consultation style focuses on 'what could be better' statements v 'what has already gone well' statements. By focussing exclusively on the former, we subtly communicate (albeit

D-6 Handbook V2

unintentionally) a message of disappointment, failure and not being good enough. Instead consider every interaction with a patient as an opportunity to motivate rather than de-motivate; to engender optimism rather than pessimism.

Reflections
According to the MI model, reflections should be presented as statements rather than questions. Once we start using reflections, it can sometimes feel more comfortable to use phrases such as 'so it sounds like …?' 'I wonder if …?' 'Maybe you are feeling…?' or allowing our voices to go up at the end of a statement to imply a question. However, by turning reflections into questions, we imply that the patient needs to respond. This can interrupt the flow of a patient's thoughts and is less helpful in expressing empathy. Reflections don't need to be responded to. However, if a reflection sounds inaccurate to a patient, they will usually let you know. See below:

P: *My husband says 'oh why don't you just take better care of your diabetes'. He makes it sound so simple.*
C: *You're angry at your husband*
P: *Not so much angry, just disappointed that he will never really understand what it's like for me to live with diabetes.*

Example 1
P: *I have tried to lose weight before and it just becomes really tedious – always thinking, 'can I eat this?' 'can I eat that?' Deep sigh*
C: *Dieting can start to feel overwhelming.*
P: *It just makes you want to put up with the pounds for an easy life.*

Example 2
P: *I have tried to lose weight before and it just becomes really tedious – always thinking 'can I eat this?' 'can I eat that?' Deep sigh*
C: *So it sounds like dieting in the past has become a bit of a chore?*
P: *Well yeah, it's always on your mind 24/7… you never get a break from it – do you know what I mean?*

In Example 1, the patient is able to move on to her current state of mind i.e. wanting an easy life. By posing a reflection as a statement, the clinician has communicated that they have understood, no response is needed from the patient and they can move on to reveal further information. In the second example, the patient feels obliged to give a response and elaborate further on their initial point. It's interrupted the flow of their thinking.

Summaries
For most of the consultation the patient should be doing most of the talking, with the clinician providing a skilful nudge in the right direction. Summaries are when the 'taking stick' passes to you. Allow yourself the time and space to be heard. Sometimes patients may feel excited that you have understood them and want to add their own comments. Gently but firmly allow yourself to be heard at this point. It can help to preface your statements, by introducing it as a summary and to avoid going off on a tangent midway in response to patient interruptions.

D-6 Handbook V2

C: *So to summarise, testing regularly does not fit easily into your life. You have been asked many times by the doctors to bring in your record book and feel somewhat embarrassed that you have an empty book.*
P: *Yeah, totally awful – like I know what they must be thinking…*
C: *Yet there are pressures in your life that make it very difficult to test and this is something that the doctors seem less aware of. You would like to think of ways to make testing more realistic for you, given the real limitations you have. What might be a helpful place to start with this?*

An MI summary usually tries to incorporate a presentation of the patient's current position (the pros and the cons) but also adds some forward momentum, in a gentle but purposive way.

D-6 Handbook V2

Active Listening - clinician HOTSPOTS

It feels like I'm doing nothing
Sometimes asking, listening and reflecting can indeed feel like 'doing nothing'. The patient is doing most of the talking and the clinician is not giving advice or problem solving. There is no obvious intervention in the conventional sense. However, the clinician is really being highly active - choosing which open question to ask, selecting what to reflect back to the patient and how to summarise the issues. The clinician may not be saying much at this stage, but what they do say will be strategic with the aim of building rapport and expressing empathy – the foundations to behaviour change. In addition, remember that the talking we are trying to elicit from the patient is itself an intervention. Patients hearing themselves articulate their ambivalence encourages them to resolve these dilemmas.

It takes so much longer
Using OARS to facilitate good listening can feel like a time consuming process. However, it is common to over-estimate how much time is passing when we are not talking. Being fully present with a patient (without an agenda) for even one to two minutes can go a long way. Research reports that patients feel more satisfied with their care and also perceive the clinician to have spent more time with them than they actually did. Done well, patients' responses to open questions will often provide the answers to specific closed questions.

Giving praise feels fake to me
As clinicians are also human beings (!) some of us also have a tendency to be overly self-critical and to neglect our achievements. It's important to be aware of when we're doing this so that we don't reinforce our patients' self-deprecation.

It will also be important to find a language that works for you. There are a variety of ways of providing affirmations - some more colourful than others. We may view this approach as artificially upbeat or sycophantic. However, a few statements delivered authentically will carry more weight than a barrage of forced compliments.

There is nothing to praise!
The most challenging patients can provoke this response. They don't seem to be making an effort to manage their diabetes and health information falls on deaf ears. How can we validate non-existent efforts? With the MI approach, we might say that effort (like beauty) is in the eye of the beholder. We look for the 'green shoots' no matter how small or fragile e.g. just attending the appointment. We may need to look outside of diabetes – how do they manage their home, their work, their hobbies, their relationships – all the time looking for transferable skills/positive attributes. We do this to create some momentum for change. By ignoring the small efforts, we join our patients in their hopelessness - a sort of psychological stalemate.

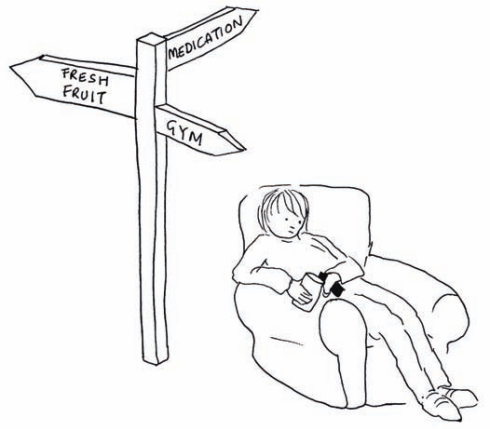
Chapter 2:
Rolling with Resistance

D-6 Handbook V2

Skill 2: Managing resistance

Why do patients display resistance?

Resistance to change can make working as a diabetes clinician a challenging and sometimes frustrating process. However, the skills of motivational interviewing are specifically designed to address this area.



The model of motivational interviewing rests on three central concepts:

- Resistance is a *normal* part of the change process
- Resistance is *not in the patient*, but in the interaction between the clinician and the patient. After all, you can't be resistant unless you have something to be resistant against!
- Resistance occurs when there is a *mismatch* between the patient's stage of change and the clinician's stage of change e.g. the clinician is in 'action' but the patient is in 'precontemplation'

Unhelpful ways of managing resistance include: arguing, raising our voice, talking over the patient, blaming the patient, labelling the patient and giving up on the patient. This is often the consequence of feeling disheartened that a patient is rejecting our help or not listening to good sense. Learning the skills to address resistance not only makes change more likely to happen but it can also enhance our own levels of motivation and job satisfaction.

D-6 Handbook V2

Obvious forms of resistance include aggression/hostility, not taking medication as prescribed or avoiding appointments. However, resistance appears in many guises and we should also be on the look out for less obvious forms of resistance which can include:

- Changing the subject or giving irrelevant details
- Promising to make changes and not following through
- Perpetually turning up late for appointments
- "Yes, but …." patient responses
- Passive behaviours e.g. one word answers
- Minimising concern or down playing problems

These are subtle ways that the patient can re-gain some control over the pace and direction of the sessions. These all indicate that we may not be in the same place as the patient, that the patient is struggling and that we may need to change tack.

D-6 Handbook V2

Managing resistance – WHAT to do

The techniques to manage resistance are divided into three categories:
1) Dealing with barriers - when there is active resistance
2) Dealing with avoidance - when there is passive resistance
3) Dealing with heated situations - when the emotional temperature is high

Dealing with barriers

This section is for situations when the patient's talk returns again and again to the barriers they are facing. It may sound like a 'yes, but' conversation or a catalogue of reasons why the patient feels they can't change. They may refer to life events, unhelpful family members / medical professionals, inconvenience, stigma and discomfort.

Remember that in these situations, the patient is actually thinking very hard about change. It is only because they are considering the possibility of change, that they are starting to see the obstacles and this can signal a step forward. In these situations the patient may be feeling overwhelmed, confused or even hopeless. The task is to express empathy at the difficulty of the situation, whilst at the same time looking for areas of hope and possibility.

MI introduces the concept of 'rolling with resistance'. This involves suppressing our knee jerk reaction to react to resistance. Rolling with it means having the knowledge that change is a process which takes time, involves backward and forward steps and that resistance is malleable. Consequently, we treat resistance as something to side step rather than confront. We choose not to give it too much attention.

Selective attention

This is a type of complex reflection. It involves selectively reflecting back the 'green shoots' from a mix of positive and negative comments.

> *P: I just hate injections, so I suppose that puts me off. I mean what other condition do you have to inject yourself X times a day? It's such a hassle, although I suppose the pen thingy makes it easier.*
>
> *C: Injecting is not a pleasant experience for you, but you're also aware that some needles could be a lot worse. Tell me more about what makes the pen easier to use.*

It is tempting here to talk about other conditions where the treatment could be worse, feel aggravated that without insulin they wouldn't be alive, or feel that you're supposed to join in the argument or agree that nothing is fair.

D-6 Handbook V2

P: It doesn't help that my husband is not interested in healthy eating. When he shops – the fridge is full of junk food. I mean if I didn't have to contend with that, life would be a lot easier.

C: You are concerned about having healthy food in the house – tell me about when you go shopping

In this example, we could have chosen to confront the patient i.e. "you may not like it, but you have to contend with it, so how are you going to manage?" But then we miss the opportunity to expand on times when healthy food is bought. Consequently, we side step the barrier for change (i.e the husband) for now. You may choose to return to this issue, once the resistance has reduced.

Positive reframing

This type of complex reflection gives you the opportunity to present an alternative interpretation of an event. It can be helpful if the patient can only see the negative viewpoint, which is keeping them stuck

P: I think my wife thinks I bring on the hypos myself
C: Your wife sounds concerned about your health

This reframes the wife's comments as possible concern rather than being accusatory. Positive reframing helps to steer the conversation into more hopeful and optimistic waters.

P: With diabetes, you have to pay so much more attention to everything – even your feet! I spend half my life seeing doctors.
C: There are lots of people paying close attention to your health to give you the best quality of life.

P: They say I need to take Metformin – I suppose they wouldn't say it if I didn't need it, but I feel fine.
C: It's good to hear that you're not feeling unwell at the moment.

With these examples, it is easy to take the bait i.e "doctors are only trying to help you for your own good" or "but you're not fine, and here's why …." However, the latter responses can fuel further resistance as the patient defends their position from attack.

P: I hate testing my blood sugars – feels so miserable when you see a high blood sugar, and you think, oh god, what's happened now?
C: You are conscientious about getting your blood sugars near to target

Again, one might have chosen to respond to this patient by providing more education about why they should be testing their blood sugar. However, this would miss the opportunity to highlight the positive aspects of his experience and therefore engender hope and minimise resistance.

D-6 Handbook V2

Overshooting reflections

In this type of reflection – you overshoot i.e. use stronger language to create an opportunity for pro change talk.

P: I know I should try and think about smoking, but it's tricky, I enjoy my cigarettes - sometimes I think it's my only pleasure in life
C: Giving up smoking will be an impossible task.
P: Well I know other people who have managed it, so …

P: I don't have a problem managing my diabetes
C: There's no room for improvement whatsoever
P: Well, I guess I don't always eat the right things

P: I've never been a gym person, I can't see myself doing anything like that
C: So there's absolutely no form of activity you would consider
P: No, not formal exercise as such, but I suppose I could do more with the dog

Avoidant situations

This section is about situations when patients deny or minimise any difficulties with their diabetes management. They may say very little, or get defensive or just divert you onto what's going well. Remember in these situations it's highly unlikely that the patient doesn't perceive there to be a problem, in fact quite the opposite. The problem seems so insurmountable that denial can help them cope with it. Your task is to gently guide them towards acknowledging some ambivalence. If a patient won't engage with you about their diabetes, you may need a lead to help you get a foot in the door. Here are some useful techniques.

Typical day question

This is useful for patients who do not say much or find it hard to reflect upon their behaviour and the consequences. Often talking about practical events/activities can be an easier place to start

C: In what ways has diabetes affected your:
Physical health
Moods / feelings
Family / partner
Social life / friends
Education / career
Spiritual life
Financial security

Refer to areas that you know are of particular interest to your patient e.g. their job; their grandchildren; their dance lessons; their driving. Use specific questions about how reported symptoms e.g. having a hypo, being thirsty, being tired, needing the loo a lot, blurred vision affect their functioning in these areas.

D-6 Handbook V2

Values Question

For people in the precontemplative stage, it can be helpful to start them talking about other areas of their life / their values and see how diabetes impacts on that. This is in contrast to working the other way round (as you might do with more motivated patients) i.e. starting with diabetes and seeing how it interferes with their life/values.

P: I got a touch of sugar but it ain't so bad. The numbers go up and down all the time, you know. I feel pretty ok at the moment and my doctor said my blood pressure is down.
C: So it's a bit of a mystery why you're here.
P: There's really nothing to worry about – you doctors always getting worried over summit. I have my two eyes, my two legs and my mental faculties (pointing to head)
C: So physically you're fit as a fiddle, you're not noticing any unwanted symptoms from your diabetes. But I'm interested in how diabetes may or may not affect all parts of your life and not just your body. Could I do a little card sorting exercise with you?
P: Ok

P: My family would be my top priority
C: Tell me more about that
P: Well I always put my children first. They are the most precious thing.
C: How do you spend time with your children?
P: Well they're grown up now (laughing) so really they're adults. I see them some weekends – they come over with their families
C: So you have grandchildren too
P: Oh yes, plenty of those
C: Family is a big part of your life, and you enjoy the time you spend with them. How might diabetes get in the way of this?
P: Well I've seen people in wheelchairs – I don't want to end up like that. But at the moment I feel fine.
C: What's your understanding about how people end up in a wheelchair?
P: Their diabetes had got bad
C: I'm wondering whether it's possible that those people also felt fine like you at some point?
P: I guess so … maybe things just got worse for them.
C: You recognise that diabetes can progress and get worse for people, sometimes leading to needing a wheelchair. That's not somewhere you want to go.

C: Can I show you a diagram[2] that some people find helpful?
P: OK
C: These are some of the ways we think we can slow down diabetes. What areas seem relevant to you?

[2] See Menu Options handout (Appendix)

D-6 Handbook V2

P: Well I don't smoke, I eat ok I guess, I do a spot of walking I suppose that's exercise
C: You sound as if you have a good grasp of the basic concepts, that healthy eating and exercise are very important, but you still have some specific questions about the details. Have I got that right?
P: I just need to avoid the chocolate bars don't I?

The clinician how has a way in – an opening has been created about an issue that the patient wants to know more about.

Normalising

This is about highlighting the difficulties in managing diabetes and that poor adherence to healthy advice is not unusual. If patients feel they are not being singled out as the only 'culprit', they can be more open to a dialogue about their difficulties.

Patient with a disabled child – clinician suspects that they are not taking medication:

C: So you must get really busy in the afternoons taking care of your daughter
P: Oh yes, my mind is always somewhere else
C: When people have other pressures in their life, it's not unusual to forget their insulin – how is that for you?
P: Sometimes it does slip my mind, yes

In this example, the clinician offers a statement describing what can considered as the 'norm' or a generalised way of behaving. This gives the patient 'permission' to talk about her own omissions. Another way to normalise the difficulties of managing diabetes is to ask the patient if they know anyone else who has diabetes and what problems and coping strategies these other patients use. The purpose here is to encourage the patient to express the challenges that other people might also face.

In heated situations

Sometimes the emotional tone of a consultation can feel quite heated. In these situations, it would not be unusual to feel antagonised. The task is not to engage in the battle, thereby fuelling the fire, but to de-escalate the situation.

Simple reflection

In the heat of the moment, it can be helpful to simply reflect back what the patient has said. It also gives an opportunity to make sure you have understood what they have told you, as an emotionally laden statement may be less coherent.

P: I'm fed up with diabetes. I just don't want to think about it anymore, ok?
C: You've had it with diabetes and talking about it makes you feel worse.

(You could move on to the values exercise – see Appendix)

D-6 Handbook V2

P: I don't want another meter, because I'm not going to test my sugars, so there's no point.
C: Right now, you don't want to do any blood glucose testing, so it seems silly for me to give you another meter.
P: Yeah, exactly.
C: What feels like a more useful area for us to talk about today?

(You could refer to the menu options here – see Appendix)

Taking a one down position

This means acknowledging shared responsibility for the situation. It is useful when the consultation feels very hostile. By the clinician acknowledging some responsibility, the patient no longer needs to attack or justify – this provides a temporary reprieve. Taking a one down position removes some of the heat out of the interaction and steers the consultation towards move constructive ground.

P: I'm ok with my diabetes - I do what I'm told, I don't know why these blood tests keep coming back so bad. (spoken forcefully)
C: I'm sorry to hear that. We have obviously failed you in some way, because your sugars are still running high. What information would you find helpful to hear from me today?

P: It's not my fault they're running high, everyone gets high readings sometimes.
C: You're absolutely right. No one can be expected to get it right 100% of the time.

P: I've got to see you now have I? I've just been waiting over an hour in the hospital. Nobody tells you what's going on. I suppose you're just going to have a go at me about my diet or something.
C: I'm really sorry that you've had to wait so long and that nobody's been communicating with you. That doesn't sound like you've been treated very well. How can we make the next 30 minutes useful for you?

These examples highlight powerful ways to defuse the situation and minimise patient defensiveness.

D-6 Handbook V2

Managing resistance – HOW to do it

With Motivational Interviewing, the clinician does not feel obliged to answer a client's objection or resistance. Instead we side step, roll with, highlight the 'green shoots' rather than the weeds. By holding this position consistently something will finally shift in the consultation – creating momentum for change. In contrast, by confronting or challenging anti-change talk, we are giving our attention to the wrong behaviours.

It is important to be aware of what not to do when managing resistance. This includes taking resistance personally. If necessary, take a breath or provide a summary to create some mental space. Remember it is not anyone's fault when there is resistance in the room – it just describes the interaction between you *both*. Try and assume that the patient is ambivalent - we just need to find the pro change statements.

In MI, resistance is viewed as useful information. It is a signal for the interviewer to shift their approach. In this way, resistance is not viewed as 'the enemy' but as a signpost. Viewing resistance in this way means we are less likely to be punitive towards ourselves and also to the patient. Being worn down by resistance can be draining and dispiriting, whereas being 'informed' by resistance can allow us to work more constructively with the patient.

D-6 Handbook V2

Managing resistance – clinician HOTSPOTS

These patients don't really want to change
Well this might be true, but it might not. By giving people the benefit of the doubt, we have something to work with. Always assume the patient is ambivalent – that part of them is considering change.

Why should I be the one apologising?
If a patient is angry or not managing their diabetes more actively, it can feel quite uncomfortable or even insincere for you to be the one to apologise. However, taking a one down position is a way to signal to a patient that arguing with you is a futile exercise. Offering an apology can quickly de-escalate a situation, and make room for a more productive conversation.

They just need to listen to reason
Patients definitely need to listen to the reasons to take care of their health. However, information which falls on deaf ears is no use to anyone. Therefore, the timing of when you provide the information is important. Taking the time to reduce the level of resistance in the room is a vital first step *before* providing further diabetes education.

They just need to be scared
Scare mongering is a seductive technique! If we can raise people's fear levels it might just jolt them into action. The problem with this is twofold: people who can't manage anxiety very well may slip further into avoidance and denial. Scaring them will reinforce this unhelpful way of coping with difficult things. Secondly, fear driven behaviour change may work in the short term, but not in the long term. When patients have a lapse (which is a normal part of the change process) they may anticipate more 'fear talk' from the clinician, meaning they are less likely to come back and be honest about their struggles.

I can't be that calm all the time!
We, like our patients, are human and fallible – prone to losing our temper, feeling hurt or saying something insensitive. This is the norm. The point of these techniques is to increase the likelihood that more of your consultations will be constructive. This will never be 100%. Beware your own black and white thinking (see Chapter 5)!

They keep going back to the same old excuses – it's like listening to a broken record
If patients keep returning to anti-change statements and it feels like you are covering the same ground at each consultation, you may need to take a more pro-active stance to addressing these barriers. Often patients repeat issues if they aren't sure that they have been properly heard or understood. This is a sign that the patient needs more active listening. Going back to the OARS, slowing down the pace of change and expressing empathy may help you move beyond this impasse.

Chapter 3:
Directing change

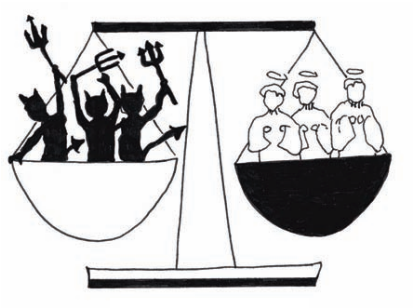
D-6 Handbook V2

Skill 3: Directing change

Why is directing change important?

Although motivational interviewing is about listening to the patient in an empathic manner and respecting their autonomy, it is *also* about directing them towards change.

In order for anyone to change they will need to have considered the reasons for change and weighed them up against the losses in making that change. Being in two minds i.e. ambivalence is a normal part of the change process. The problem with ambivalence is that people can get stuck there. They may think of one argument for change and then another argument against change ("yeah but, no but"), and it's as if they cancel one another out. If patients can't resolve their ambivalence, they may stop thinking about the issue altogether.



Ambivalence

Your OARS will help in keeping you afloat in the consultation and steer you and the patient in the direction you want to go. However, they may not get you to the final destination. Directing change is a strategy aimed towards resolving ambivalence. It involves raising awareness of the pros and cons of making a change, strengthening the pro-change talk and highlighting the incompatibility between the current situation and the patient's values or goals.

It can be summarised as:

- Eliciting change talk (DARN Questions)
- Amplifying change talk
- Activating change talk (CAT Questions)

D-6 Handbook V2

Directing change – WHAT to do

DARN Questions

You can direct change by getting the patient to tell you *their* reasons for change. The trap we often fall into is to tell patients why they should change. If we give patients the reasons to change they are left either to passively agree or to resist through a "yes, but …" answer. Neither option engages the patient constructively. By doing all the talking, we also deprive the patient of the opportunity to hear themselves articulate their reasons for change. According to Bem's self perception theory, verbalising this out loud is an important mediator for change.

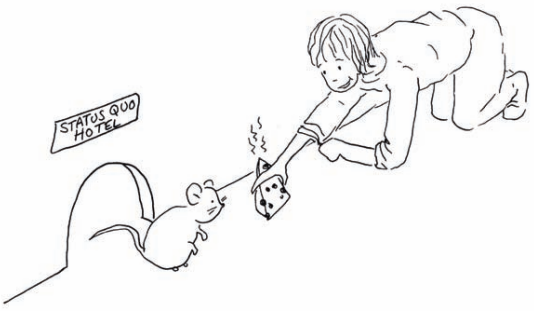
The drivers for change can be summarised as DARN- CAT*:

D – Desire: "want" "wish" "like"
e.g. I would like to get better control of my diabetes
A – Ability: "can" "could" "able"
e.g. My sister could help me with baby sitting
R – Reason: Stating a specific reason for change
e.g. Better control would mean I feel less tired during the day
N – Need: "need to" "have to" "must" "important"
e.g. I need to get better control of my diabetes

*CAT statements are considered in the next section.

These are all examples of *preparatory* talk – laying the mental foundations on which to support behaviour change. Questions that elicit DARN statements from a patient will be fuelling the "human engines for change" (Rollnick, Miller & Butler, 2008, p.40). Here are some examples of questions to elicit change talk around diabetes:

Why would you want to slow down your diabetes? (desire)
How would you do it, if you decided to? (ability)
What, for you, are the three best reasons to get better control? (reason)
How important is it for you to make these lifestyle changes? (need)



D-6 Handbook V2

By asking these questions you are not only eliciting change talk, but also have an opportunity to check out the patient's understanding of their health education (more on this later in Chapter 5). In addition, you are connecting with *their* values. For instance, we might think that reducing the risk of a heart attack is a major reason to give up smoking, but the patient might be more motivated by the thought of saving money or nicer smelling breath.

There are tools you can use which will extract similar information to the above questions. These are the readiness/confidence rulers (see Appendix) and the Decision matrix (see Appendix). These tools will help explore a patient's ambivalence – eliciting the reasons for and against change. If a patient is able to come up with reasons for and against change, you may choose a **double sided reflection** (this is a type of complex reflection) to reflect their ambivalence. See example below:

C: What concerns do you have about taking your insulin?
P: Insulin makes you put on weight
C: So you feel heavier from taking insulin. How does being overweight affect you?
P: I don't fit into my clothes, and I can't move about easily and my joints they really hurt.
C: So there's a sense of feeling bigger and less mobile when you're overweight, but on top of that, you're telling me that it leads to pain. That must be very distressing. That must make you want to avoid the weight.
P: Yes I do
C: I guess there is a dilemma – on the one hand you recognise a need to take your insulin, on the other you feel it will lead to weight gain.
What benefits might insulin give you?

In the last two sentences the clinician delivers a double sided reflection and follows this with a question to elicit more change talk.

Amplifying change talk

When you hear change talk, don't just sit there, say something! Remember that any signs of change talk coming out of the patient's mouth are like young shoots struggling to grow. Without water or sunshine they will struggle to thrive and may be overtaken by weeds. Our task is to amplify the change talk, so that it starts to carry more weight than the anti-change talk. Amplification can happen in a number of ways:

1) **Provide affirmations** i.e. statements of support for pro change ideas e.g.
   It's great that you see the value of attending your appointments
   You're thinking really hard about how to fit exercise into your life
2) **Encourage elaboration** e.g.
   How did you manage that?
   How did it feel?
   Why would that be important to you?

D-6 Handbook V2

3) **Selective attention**

Your task here is to look out for the pro-change statements amidst the anti-change talk (see Chapter 2)

e.g *P: I can't really cook and so I tend to buy junk food – usually too knackered to think about anything else after work. I don't think I'm a junk food addict – I can quite happily munch on carrots and stuff like that, but it's a lot easier to grab a chocolate bar on the way home.*
C: If healthy food is presented to you, you don't mind eating it. When do you come across stuff like carrots?

The clinician is selectively reflecting back the positive angle i.e. the patient enjoys eating healthy food and then asks them to elaborate on how they might come across healthy food. In this example, there is some rolling with resistance.

You can also apply the above techniques to amplify anti-sustain talk i.e. a statement that reflects the downsides of not changing. Consider these examples:

P: This can't really go on I know.
C: What is it that needs to change?
P: I'm just tired all the time, and have ended up in A&E a few times
C: What do you imagine will happen if this continues?

P: I suppose my eyes are already showing some changes – I wasn't really expecting that.
C: What does that suggest to you?
P: My diabetes is racing on ahead - more than I thought.

In both examples, the patient is starting to hint at the negative sides of having poorly controlled diabetes. Instead of letting this pass, the clinician is using elaboration to strengthen the anti-sustain talk i.e. encouraging the patient to talk further about the disadvantages of not changing their behaviour.

CAT Questions

The following are examples of *implementing* talk – statements that suggest the patient is ready to consider action.

C – Making a commitment: "will" "intend to" "going to"
e.g. I will renew my insulin prescription
A – Activation: "ready to" "willing to" (without specific commitment)
e.g. I am willing to test more frequently
T – Taking steps: Reporting recent action towards change
e.g. I signed up to join a gym last week

Commitment language signals the strength of change talk. For example, a patient may say "yes it's important for me to put diabetes first (*need*)" or "I would like to be slimmer (*desire*)" or "I could buy healthier ready meals (*ability*)" - none of these statements are providing an actual commitment towards change. The task here is to

D-6 Handbook V2

support the patient in translating their 'good' intentions into action (i.e. a preparation phase in the cycle of change)

The following are examples of questions to move patients towards activation:

Where could you go from here?
Who could help you with this?
What do you intend to do?
What are you going to do next?
What would you be willing to consider?
What could be your first step?
What feels like a reasonable change/goal for you to make?
What feels manageable/realistic for you?

Check out with the patient what are the obstacles/barriers to change occurring:

What's preventing that happening now?
What's stopping that being the case?
Who / where / how are the obstacles preventing you from getting the outcome you want?

Help the patient to start problem-solving around this (more on this in chapters 4 and 6)

What might be a way around this?
What needs to change for you to move forward with this?
Who/what could help you with this?

Knowing when to ask questions that are action-oriented will be a matter of timing and clinical judgement (see How to section below).

D-6 Handbook V2

Directing change - HOW to do it

In order for a patient to resolve their ambivalence, they need to see a good enough reason to change (eliciting and amplifying change talk) and to believe that they *can* change (activating change talk).

Eliciting and amplifying change talk
The key to directing change is to adopt the mindset that the patient has the answers. The patient needs to convince *you* of the reasons why they should change, rather than the other way around. This means they need to come up with robust evidence, like a lawyer presenting their case in court, as to why change is worthwhile. Remember that the more patients verbalise why they should change, they more likely they are to change their behaviour. Your task is to simply facilitate this process by asking the sorts of questions that will elicit change talk. However, don't forget to intersperse your questions with reflections, or the patient could feel they are in a firing line of questions.

Managing ambivalence
As soon as a patient has given you a reason for change, they may come up with another reason to cancel it out. You may need to spend more time than you think in the land of ambivalence. This means reflecting on the pros and cons, expressing empathy in relation to the difficulties and strengthening the pro-change talk. At this point, the clinician should normalise this process – letting the patient know that ambivalence is normal and that attachment to 'unhealthy' behaviours is not unusual. Things may feel like they have stalled at this point. However, by gently but consistently reflecting the current dilemma (e.g. inconvenience 'v' poor health) back to the patient you will start to generate some internal momentum (see Appendix on Cognitive Dissonance). Think of this *preparatory* talk as the scaffolding without which the 'house of change' will collapse.

Activating change talk
Timing is a crucial factor in directing change. If you move to 'action' prematurely patients may feel threatened, misunderstood or inadequate, leading to disengagement.
As always, your patient will be your best guide as to when they are ready to implement change. Listen out for when there is some momentum towards change i.e. when you hear the DARN-CAT statements coming from the patient's mouth (not yours!). Only when you hear pro-change talk emerging, might you could consider dipping your toe in the water of 'action'. This means supporting patients to think about how they will translate their 'good' intentions into action.

D-6 Handbook V2

Directing change – clinician HOTSPOTS

Asking DARN-CAT questions – What if patients just tell me what I want to hear?
This may be the case at first. However, as the patient learns to trust you, they will take the risk to say things that move away from 'textbook' answers. If trust is an issue, the focus should be on building up further rapport with the patient through active listening.

Thinking about pros and cons of change – what if the patient doesn't see any pros?
If a patient cannot think of any good reasons for change, try some further exploratory questioning. Areas to consider are:

Why they have come to see you today?
What they imagine life could be like if their diabetes was better controlled?
What other people who are close to them feel about their diabetes?

It is possible that patients are genuinely unaware of the positive benefits associated with improved diabetes control. This can be provided through further diabetes education or sharing the benefits other patients have reported. In Motivational Interviewing information can be provided to the patient, after seeking permission first (see chapter 5)

Thinking about pros and cons of change - what if the patient feels the cons outweigh the pros?
Again, you will want to explore exactly how the patient has reached this conclusion to check for any inaccurate or missing health information. Ways to do this are considered in chapter 5. After considering all the pros and cons, a patient may decide it is not worth changing their behaviour and this is something they are within their rights to do. This can be a bitter pill for clinicians to swallow. However, it is worth considering whether the patient may be more amenable to change at a different time in their life (e.g when their domestic situation is more stable) or whether the goal can be modified (e.g. aiming for a smaller drop in HbA1c)

What if I ask about goal setting before they are ready?
If a patient is not ready for goal setting – they will signal this in some way e.g. not completing the goal, not attending the appointment, going quiet etc. It is normal for clinicians to get it wrong sometimes and to prematurely push a patient towards action. The important thing is to pick up on the feedback you are getting from the patient so you have an opportunity to change tack and rescue the situation. The art of MI is being responsive to any feedback (negative or positive) the patient gives you and using this to guide your next move.

An Interlude: Thinking about learning

D-6 Handbook V2

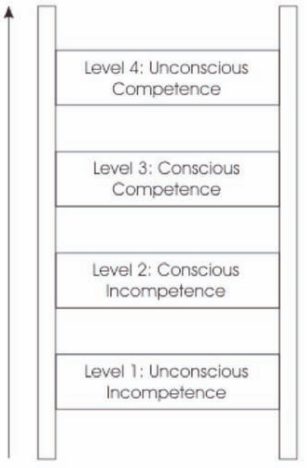
Learning new skills

I'm not sure about this psychology stuff!
At this point and before you launch into the rest of the handbook, it may be worth thinking about the process of learning itself. You may find that your head is already spinning with all the new concepts, words and jargon you have just read and how you might fit this into your practice. Learning the D6 skills will involve some changes to your established practice. Therefore, we are not just talking about changing our patient's behaviour but also changing our own!

We now know that the process of change comes with ambivalence and is not an 'all or nothing' concept. There will be some aspects you are keen to change about the way you communicate with patients, and others you are reluctant to let go off. It is important to acknowledge that being in two minds is a normal part of the process. In addition, take a moment to reflect where you might be on the Stages of Change model – are you in action or contemplation or somewhere else? Observe how your position on the change cycle may vary, going forwards as well as backwards as you proceed through training.

Will I ever 'get' it?
Even if one is motivated to acquire new skills, this motivation can soon dwindle as the reality of making mistakes, feeling incompetent and possibly hopeless kick in. Maslow outlines the stages involved in learning a new skill. See below:

Figure 1:
The Conscious Competence Ladder

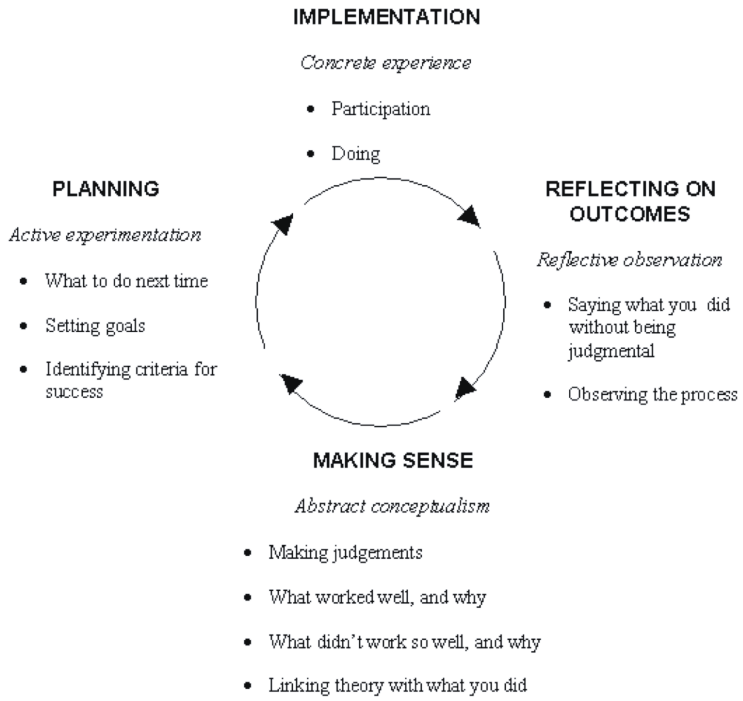


D-6 Handbook V2

It can be helpful to keep this model in mind to prepare yourself for the peaks and troughs that inevitably arise from leaning a new skill. During the first stage you may be 'blissfully' unaware of what you don't know (unconscious incompetence). During the process of learning you become conscious of what areas are lacking (conscious incompetence). When you start to consciously change how you respond to a patient, to try something different and see the results, this can be rewarding and uplifting (conscious competence). Over time and with consistent practice, your skills become more ingrained, your instinct improves and the responses come more easily. Eventually, you may lose sight of the skills that you have gained because they become so automatic. (unconscious competence).

Kolb learning cycle
How do we learn a new skill? The old fashioned way of 'chalk and talk' i.e. being taught information whilst we listen passively is not always the optimal way to learn. What is missing is the component of experience i.e. of having a go ourselves. This experience is unique to each individual and will highlight for them what went well, what needs tweaking and what's to be avoided for next time. This process of feedback and reflection is very important for learning to occur. See diagram below:

Kolb Learning Cycle



D-6 Handbook V2

One of the key phrases to highlight is ‘saying what you did without being judgemental’. All too often, especially in those who are highly conscientious, the feedback stage can be overly critical or berating of our ability “I should have …” “ I’ll never get it” “I’m so stupid”. The process of learning simply requires that we view the data objectively and consider what we might do differently the next time, without the need for unhelpful judgements or labels. The experience of mistakes/set backs is part of the process it’s expected and fertile learning ground.

Chapter 4:
Supporting Self-efficacy

D-6 Handbook V2

Skill 4: Supporting Self-efficacy

Why is supporting self-efficacy important?

Self efficacy is defined as a person's belief in his of her ability to carry out a specific act or behaviour. It comes from Albert Bandura's social learning theory in the 1980's. In an MI context, it is about increasing a patient's *confidence* in their ability to make changes. One way to quickly undermine this confidence is to provide all the answers for the patient. This subtly communicates the message that the patient doesn't have their own resources.

In behaviour change work, supporting self efficacy is about helping patients to come up with their own solutions to the problems they raise. It follows from the idea that although we are the experts on diabetes and general principles of behaviour change, the patient is an expert on themselves. They will know what will and won't work for them, and what has worked for them in the past. They will also know how much change is feasible for them, given their current commitments and limitations - although we may gently nudge and shape those intentions.

A patient's confidence in their ability to make changes is an important mediator for long term change. Firstly, they can set the rate and amount of change that feels comfortable for them, giving a greater likelihood that they will achieve it. Secondly, by asking questions that ask patients to think for themselves, it demonstrates that you have confidence in them and their resources to make change. The sense of achievement is likely to be greater if patients can come up with their own ideas. Thirdly, it helps patients become more self reliant in the long term, and less dependent on their healthcare provider. In addition, self efficacy is a transferable skill than patients can apply to or from other areas in their life.

Very often a patient's sense of self efficacy can be low during their diabetes consultations. This is because they may expect the healthcare professional to tell them what to do, and also because they may have already experienced failed attempts to self regulate their diet, exercise levels and insulin needs. A low sense of self efficacy (and often self esteem) can be associated with feelings of hopelessness and is a maintaining factor in depression. Hence, by supporting self efficacy you are not only helping the patient manage their diabetes but may also help to alleviate mild to moderate symptoms of depression.

D-6 Handbook V2

Supporting self efficacy - WHAT to do

Supporting self efficacy is more about the particular attitude we adopt with patients, rather than a specific technique (see How to do it). However, there are some useful questions which can help us move forward in our consultations.

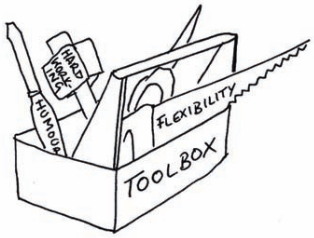
Affirmations

Supporting self efficacy draws on making affirmations. These are the points where you can highlight what the patient has already achieved and make explicit the link between their actions and positive consequences.

> *C: Given you're under the weather and didn't fancy coming here, how did you manage that?*
> *P: Well I thought I might feel better if I go outside and it might make me feel like I'm doing something positive for my health*
> *C: How do you feel now you're here?*
> *P: Yeah, I'm glad I made the effort actually*
> *C: Telling yourself to come here, even though you didn't feel like it was a useful strategy.*

In the above example, for instance, the patient has demonstrated that low mood can be temporary, that positive self talk (ie. telling yourself motivating statements) can lead to action and that there may be benefits to doing something that you may not feel like doing initially. These are all areas that could be later applied to his/her diabetes control.

To support self efficacy through affirmations, you are asking the patient *how* they managed to achieve something and *what* the consequences were. This reinforces their role as an active, effective agent in the world i.e. things just don't happen to me, **I** can make them happen. Use every opportunity to find out a patient's personal toolkit of resources. You may have to look outside diabetes initially to find them e.g. being a mother, effective employee, good friend.



D-6 Handbook V2

Solution Focussed Questions

Solution focussed questions are useful at later stages when the patient is starting to think about making changes. By asking these sorts of questions, you are hoping activate a different sort of change talk: C A T

C Commitment (Will, intend to, going to etc)
What do you intend to do?
A Activation (Ready to, willing to – without specific commitment)
What are you ready or willing to do?
T Taking steps (Reporting specific action/steps towards change)
What have you done already?

Further types of questions to help patients draw on their own resources are listed below:

Using past experience (useful in the 'preparation' stage of change)

What have you found has worked for you before?
Was there ever a time when you were having more success with this? Tell me about that ….
What factors support you with this?
What factors get in the way?
Who has helped you in the past?
When are you more likely to make progress with this?

Using other people

Who could support you with this? How might they best support you?
What might you say to a friend in this situation / facing this obstacle?
Imagine other patients with diabetes were listening to your dilemma – what might they say/do/suggest, if they were here?
What might your best friend/wife/family member say is the way forward?

Using hypothetical scenarios

Imagine that you felt more in control of your diabetes, what would need to change to enable you to feel that way?
What do you think is standing in the way of that?
What do you think would work for you on this?
If you were feeling less stuck, what do you imagine might be the next step forward?

Making suggestions

Sometimes patients will find it impossible to think of a way forward and you may find yourself needing to make a suggestion. However, always check in with yourself:

- Have I really given the patient enough opportunity to come up with their own ideas?
- Is this the 'righting reflex' creeping in through the back door?
- Am I rushing the session on?

D-6 Handbook V2

There are ways we can limit the potential damage of making suggestions:

1) To view suggestions as a last resort
2) To ask for permission before we offer them

We ask for permission because it honours the patient's autonomy, it seeks their active involvement in the information exchange and it lowers resistance i.e. you are not foisting upon them anything they didn't agree to.

Would you like to hear about some things that other patients have found helpful?
Would it be ok if I tell you one concern I have with this plan?
There are several things you can do to keep your blood sugar levels under control. Do you want to hear them, or are there other things that we should talk about first?

D-6 Handbook V2

Supporting self efficacy - HOW to do it

In order to support self efficacy in our patients, we need think about the questions we ask, how we ask them and to suppress a very natural tendency to give advice. Certain questions (such as those above) encourage patients to reflect upon their own resources. They should be asked with an open, curious attitude which models a belief that patients do have their own resources (albeit unexpressed) and that it is our task to elicit these. As this approach will be unusual for most patients, it may require some gentle persistence on the part of the clinician to encourage this way of thinking. For instance, approaching the question from a few different angles.

> *P: I keep forgetting to take my tablets. I only see what I've missed the day after.*
> *C: So forgetting your tablets is something you've identified as a problem. What would make it easier for you to remember them?*
> *P: No idea*
> *C: Have you ever managed to take them more regularly?*
> *P: No*
> *C: Say a good friend of yours was having the same dilemma – forgetting their tablets – what might you suggest to them?*
> *P: Oh I might suggest they were losing their marbles like me (laughing)*
> *C: You seem to manage very well in many aspects of your life. Would you make any practical suggestions to your friend?*
> *P: Well maybe they could take them at a certain time of day, with a TV programme or something*
> *C: And how might that work for you?*
> *P: I've never really thought about that. I suppose I watch Coronation Street religiously …*

After each initial 'no' response, the clinician could have exited the conversation, or jumped in with a suggestion, but instead he/she gently perseveres so that the patient can come up with their own idea.

Beware the 'righting reflex' – when you sense you are slipping into 'you should' 'you must' 'why don't you …' you are moving towards an authoritarian stance. It is easy then to fall into the question/answer trap which can fuel a 'yes, but' line of conversation or silence an already passive patient. A useful rule of thumb is the **'three strike rule'**. This means asking the question three different ways, before changing tack or offering a suggestion.

Supporting self efficacy should be highlighted throughout e.g. though affirmations. However, beware of timing in relation to moving towards action. The solution focussed questions outlined above are for patients who have started to resolve some of their ambivalence and are starting to think about change in more concrete terms.

> *P: I know about all these horrible complications. But my life just gets too hectic sometimes, you know. The injections just slip down the priority list.*

D-6 Handbook V2

C: So what might you say to a friend about this problem?
P: You're screwed?

At this point, reflections and exploratory questions may be more useful to build up rapport and to reinforce the patient's confidence/desire to change:

Versus

P: I know about all these horrible complications. But my life just gets too hectic sometimes, you know. The injections just slip down the priority list.
C: You recognise how important the injections are for your long term health, but you're struggling to fit them into a very busy life.
P: Yeah exactly.
C: Tell me more about why you feel the injections are important?
Or
C: Tell more about how you manage to juggle the different areas of your life?

In this example you are looking for change talk (*Desire / Reason / Need*) or skills/strengths (*Ability*) than can be applied to diabetes care. It is a more appropriate strategy (given where this patient is at) than asking them to think about steps toward action.

D-6 Handbook V2

Supporting self efficacy – clinician HOTSPOTS

What if they don't come up with anything?
It is quite possible that some patients will struggle to come up with their own ideas. The danger is to assume that all patients are like this or to give up at the first hurdle when asking about their ideas. In situations where the patient seems genuinely stuck, it is not off limits to make suggestions (see above).

But I'm the professional / expert in this relationship!
There is no doubt that you hold a vast amount of expertise about diabetes and how to manage it. However, our task here is behaviour change. If we are talking about the patient's behaviour, then it will be the patient who knows themselves best**.** Ultimately they are in charge of their own life, and must make an informed choice about whether to prolong its quality.

Sometimes you have to take charge e.g. DKA / a severe hypo
Without a doubt, there are times when the clinician needs to take charge and it would be inappropriate to have a lengthy discussion or ask the patient to come up with their own solutions. This mindset is appropriate for emergency / rapid response situations. A question to ask ourselves is: are we leaping into the same 'emergency mode' for long-term lifestyle changes?

What if their suggestions are 'wrong', ill advised or inappropriate?
A patient may decide to cut out all sugar from their diet or to tackle their exercise levels, when really you are more concerned about their poor adherence to medication. In either case you may want to intervene. There are a couple of ways to handle this depending on the clinical situation:
1) To allow them to start with something they are motivated to attend to, and look out for transferable skills
2) To allow them to start with something they are motivated to attend to, and reflect with them what could be done differently the next time
3) To ask permission to comment on their plan of action

If I just give them this piece of information, it could make all the difference
It is tempting to believe that patients don't have the knowledge to make sensible decisions, and if we just provided this knowledge, they would change. However, we know from numerous health promotion campaigns, that education isn't enough. Furthermore, it is unlikely that diabetes patients with long term poor control will be ignorant of the facts. More likely, is that patients will block out information that they're not ready to hear, which is why the decision for more information should come from them not you.

Patients want us to be the expert
When starting to work in this way, you may encounter responses such as "well if I knew that I wouldn't be here, would I?" or "I thought you're supposed to be the expert!". Some patients may seek to maintain the status quo i.e. active clinician / passive patient and feel threatened by any attempts to reverse this. This is a form of

D-6 Handbook V2

resistance which we can choose to roll with (see Chapter 2), all the while maintaining that you are interested in their perspective and believe they may have some useful ideas.

C: What might make it easier for you to avoid buying unhealthy foods?
P: Well if I knew that I wouldn't be here, would I love?
C: I think you're a resourceful woman, and I'm interested in <u>any</u> ideas you might have about this…

If I just tell them what to do, it'll speed up the whole process

This is false economy with speed. Telling patients what to do may get create the illusion that you are moving forward, that the patient has heard you, is compliant and will follow through with action. The high rates of poor diabetes control however, suggest that the information we provide does not lead to long term behaviour change.

They're too depressed

If a patient is appearing very stuck, hopeless or passive, it is even more tempting to provide them with advice/solutions. However, remember that by 'rescuing' the patient in this way, we might be inadvertently reinforcing their sense of being 'useless'. In these situations, we may need to slow down the pace of change, be gently persistent in encouraging them to come up with their own ideas and have the 'three strike rule' at the forefront of our minds. Remember that the rate of change will invariably be slower with a depressed patient than a non depressed patient. If these strategies fail, we may need to discuss this patient with a mental health colleague.

Chapter 5:
Addressing health beliefs

D-6 Handbook V2

Skill 5: Addressing health beliefs

Why are health beliefs important?

This section draws on ideas from the Health Belief Model (Lewinsohn, 2001) and Cognitive Behavioural Theory (Beck, 1967). These models make the assumption that health behaviours do not arise out of thin air but are driven, in part, by a patient's thoughts and beliefs about their diabetes. When a patient displays an unhelpful behaviour e.g. not taking Metformin, the assumption from the above models is that there will be an underlying thought/belief which justifies the behaviour e.g. I'm not really ill.

In an ideal world, health information would be translated into accurate and helpful health beliefs by the patient. In the real world however, information is often missed (e.g. that diabetes is a chronic condition), misunderstood (e.g. I must avoid all carbohydrate) or distorted (e.g. all hypos are severe) When this happens, problems in behaviour change are more likely to occur. Therefore, it is important to identify how a patient is thinking about their condition.

If we can understand the thought process or rationale underlying a behaviour, this can make the seemingly "irrational" actions of our patients more rationale. Furthermore, once we understand their viewpoint, it can help us feel more empathy for the patient, and therefore less frustrated by their 'non compliance'. Feeling empathy rather than frustration is a good place to start in supporting our patients to make changes.

On a pragmatic level, much time can be wasted when we fail to take into account a patient's individualised health beliefs and instead assume what is underlying their actions. Consider these two examples. They both start with the same scenario:

C: It seems that your symptoms really vary from day to day. Pause
Are you sometimes not taking your tablets? (spoken gently)
P: Yes, I don't always take them … usually when I'm going out

Example 1	Example 2
C: Have you thought about keeping your pills in a little box? *P: No* *C: Then you can take them with you when you go out.* Pause *Is that something you could maybe try?* *P:* Nods head	*C: I wonder what makes it harder for you to remember when you are going out?* *P:* Shrugs shoulders *C: What would be the worst thing about taking them more regularly?* *P: Well, you'll get more side effects, so I don't like to take too many.*

D-6 Handbook V2

In the first example, the clinician assumes that the issue is a memory problem. The second example reveals how a few well chosen questions have uncovered the patient's real concern around side effects. Without this probing, the clinician may have used the time to discuss dossette boxes, when the consultation really needs to be about the patient's concerns around side effects. Addressing health beliefs help make your consultations more effective by targeting the key cognitions that contribute to poor glycaemic control.

D-6 Handbook V2

Addressing health beliefs – WHAT to do

Identifying health beliefs

The first step is to identify the health belief which is maintaining the problematic behaviour. It sounds simple but can be quite challenging. Firstly, the patient isn't always consciously aware of what health beliefs they have and even if they are, may not feel comfortable disclosing them to you. In the latter case, building trust through rapport (see Active Listening section) will go some way to address this.

The *upward arrow* and *downward arrow* techniques can be used to 'uncover' less obvious health beliefs. These techniques involve asking a number of repeated questions along a specific line of enquiry. They build on the DARN-C questions introduced in chapter 3.

Upward Arrow

The upward arrow is a useful technique to identify information that the patient may be missing or misunderstanding in relation to why a specific behaviour change may be beneficial to them. The central line of enquiry is:

Why is X beneficial for you?
X being whatever behaviour the patient is avoiding.

You continue to ask this same question (maybe phrased in different ways) until a gap in knowledge is found.

Why might that be important?
How would that be of benefit to you?
Why might the doctor / I suggest this?
Why is that a good thing for you?
How does that help you in your life?

All the while, you are asking yourself what is this patient missing or not seeing or underestimating?

Consider this example

A Type 2 diabetic patient is not taking his insulin regularly, but does complain of fatigue and going to the toilet a lot. He's not sure why he needs to inject when he feels "pretty ok" at the moment.

C: Why would we recommend taking insulin?
P: To treat my diabetes
C: And how might the insulin do that?
P: It gets the sugar down doesn't it?
C: Right. And why might you think it's important to get the sugar down?
P: To treat the diabetes

D-6 Handbook V2

An upward arrow line of enquiry has revealed that this patient has made a link between insulin and treating diabetes. However, how insulin can help his day to day symptoms (which do concern him) is not evident. Therefore, he has no real rationale for taking his medication other than an abstract concept of it "treating his diabetes". It may have been tempting to stop at "it gets the sugar down" and be satisfied that this patient understands why insulin is of benefit to him. Yet, if we assume that this patient is not taking his insulin because he is missing or misunderstanding some vital information we would not be satisfied with this answer, but continue the upward arrow line of enquiry:

C: OK. So how might getting your sugar level down improve your energy?
P: I don't know actually. I mean sugar gives you energy doesn't it?
C: Would it be helpful for me to explain how we think the insulin works?
P: Yeah it would
Clinician goes on to use key/lock metaphor for insulin action and putting fuel in the engine for energy - see Appendix

In ideal world, patients would have attended some form of diabetes education. However, this is not always the case, especially with older patients, and furthermore, what patients hear and what they interpret or retain at the time can be very different. The point of this technique is to find out what the patient has understood regardless of what they've been told. Consider the following example:

A patient consistently attends appointments, but always fails to bring a record of any testing

C: So it seems it's really difficult to test regularly. Could we talk some more about that?
P: Yeah, I know I should.
C: Right, so I'd be interested to know why you think it might be important to test your blood sugar levels.
P: Well I need to write them down innit.
C: Uhuh. So you feel you need to keep a record – why's that?
P: So you can see my readings, if I'm going high or low.
C: Right – and why is it important to see that?
P: To see if I'm managing my diabetes ok – keeping my sugars low. You guys wanna keep an eye on me.

So at this point, it's not at all clear what's in it for the patient i.e how it might benefit them.

C: So you feel it's about keeping an eye on you. Tell me more
P: Well yeah if I write it down, you'll be having a go at me, about getting good numbers

So the upward arrow has revealed that the patient actually believes that this is no more than a 'big brother' exercise. It's clear now that the aim of the consultation is to link how recording data might actually be of benefit to the patient.

D-6 Handbook V2

C: Mmm, well I'm not sure you've got it quite right there.
P: Oh?
C: We do need to see the numbers but really that's for your benefit – can I explain how that might be?
P: OK.
Clinician goes on to use bespoke tailoring analogy (see Appendix)

Downward Arrow

This technique is similar to the above except its central line of enquiry is:
Why is X a problem for you?
X being whatever behaviour the patient is avoiding.

A downward arrow line of questioning was used in the first example given in this chapter.

C: It seems that your symptoms really vary from day to day. Pause
Are you sometimes not taking your tablets? (spoken gently)
P: Yes, I don't always take them … usually when I'm going out
C: I wonder what makes it harder for you to remember when you are going out?
P: Shrugs shoulders
C: What would be the worst thing about taking them more regularly?
P: Well, you'll get more side effects, so I don't like to take too many.

Other useful questions include:

What might that be a problem?
What concerns you about that?
What worries you most about?
Why is that a bad thing for you?
How does that hinder you in your life?

Your aim is to find out what is this patient overestimating, distorting or misinterpreting? The downward arrow can reveal unhelpful health related cognitions which may be keeping the patient stuck. Consider the following examples:

C: Just looking at your record book there seem to be quite a few hypos here
P: Yeah I guess so
C: How do you respond when you see those readings?
P: Oh well I usually know that my meal isn't far off
C: What would be your concern about treating a hypo straight away?
P: Erm well I just don't see the point in making a fuss really
C: It feels like an unnecessary hassle to treat a mild hypo. What sort of hassles would it cause you?
P: Well it's not so much me, but my daughter is always around you see. I think she'd worry if she saw me taking a dextrose tablet – she's knows something's up.

D-6 Handbook V2

In this case the consultation needs to be about addressing needs of the daughter e.g further education, a joint session, ways for mum to explain mild hypos to her daughter.

C:How would you feel about starting some sort of exercise?
P: I'm not really up for that.
C: What concerns do you have about exercise?
P: Nothing. It's just not my cup of tea.
C: Right. I'm really curious as the word exercise can mean such different things to different people – what would it mean to you?
P: Going down to the gym – circuits and weights. I'm not really a gym person – never felt comfortable in those places

In this case, the consultation needs to address other forms of exercise that the patient might be more willing to consider.

P: There's no way I'm going to start on insulin
C: Insulin does not feel like an option for you. What would be the worst thing about taking insulin for you?
P: Well let's just say I know people on insulin
C: Uhuh, and what have you gathered from that?
P: Well it's a hassle isn't it? You have to have injections with you when you go out. Injecting in restaurants – out and about. No way I'm gonna do that.
C: Ok Leroy... I think there might have been a misunderstanding between you and the doctor
P: Oh? What's that then?
C: Well you're right the doctor does want you to start on injectable insulin. However, he was just talking about an injection once a day, which you could give at home, before bed.
P: Just once a day?
C: Yes – would that be something you might consider?
P: Well once a day… in the privacy of my home … I would have to think about that...

In the example above, the clinician has de-escalated the situation, found out the relevant health belief and given new information (with permission). Instead of building further resistance or making assumptions (e.g. he must be scared of needles), the clinician has skilfully moved the patient from pre-contemplation ("No way I'm gonna do that") towards contemplation ("I would have to think about that …"). It might be tempting here to react to the resistance e.g. 'well insulin is what's going to control your diabetes' or stop the enquiry prematurely by making assumptions e.g. he must be scared of needles. Actually the patient is concerned about being seen in public and this gives you something to work with constructively.

Unhelpful thinking styles

It is always important to check that patients have the correct information about their diabetes and a clear rationale for why behaviour change might improve their quality of life. However, some patients may have developed maladaptive or unhelpful thinking styles which can make the thought of change very distressing. This is

D-6 Handbook V2

especially true in patients who are anxious or depressed. In this population, the same thinking style which contributes to their depression or anxiety might also prevent them from managing their diabetes more optimally.

Common thinking errors include:

Personalising	Attributing all negative outcomes to a personal deficit, often neglecting the role of other factors
Catastophising	Only attending to the worst case scenario
All or nothing	Responses are on either extreme of a continuum

The end of this chapter has a table with examples of common thinking 'errors' in diabetes. Consider the examples below which show how the same thinking style can be present in diabetes and non diabetes scenarios alike.

*If my boss shouts at me, I must have done something wrong (**personalising**)*
*If I have a 'bad' blood glucose reading, it's always my fault (**personalising**)*

*All hypos will result in me passing out (**catastophising**)*
*If my chest hurts, I must be having a heart attack (**catastrophising**)*

*If I can't go back to my old job, then I can never work again (**all or nothing**)*
*If I can't achieve consistent weight loss etc there's no point trying (**all or nothing**)*

When using the downward arrow technique it can be useful to be on the look out for these unhelpful thinking styles. With practice, they become easier to spot. There can be subtle clues in the language:

- the use of extreme words such as **always**, **never**, **no**, **all, always, everyone**
- what the patient says sounds like a rule e.g. **should, must, if … then**.
- statements have little room for flexibility, distort the facts or set the bar too high
- responses may be self demeaning or overly critical e.g. **I'm an idiot**

Consider the above examples again, with the clue words highlighted.

*If my boss shouts at me, I **must** have done something wrong (personalising)*
*If I have a 'bad' blood glucose reading, it's **always** my fault (personalising)*

***All** hypos will result in me passing out (catastophising)*
*If my chest hurts, I **must** be having a heart attack (catastrophising)*

*If I can't go back to my old job, then I can **never** work again (all or nothing)*
*If I can't achieve consistent weight loss etc there's **no** point trying (all or nothing)*

D-6 Handbook V2

Creating new health beliefs (cognitive restructuring)

Once you have a better understanding of a patient's unhelpful health beliefs, you may need to intervene at a cognitive level i.e. changing their reasoning. This is called cognitive restructuring. For some patients, this may be a relatively straightforward task of providing the information they are missing in a meaningful way. However, if the patient has an unhelpful thinking style which is distorting the information they have been given, some additional psychological tools may also be helpful (see next section).

By using the arrow techniques you can pinpoint the key misunderstanding and tailor the information you provide to address this. In providing new health information, pictures can be a useful way to explain complex information and make it more memorable. Some common misunderstandings in diabetes knowledge are outlined below with associated visual aids. However, you may well have your own visual resources for this.

The role of insulin

The patient does not really understand the importance of taking insulin and its role in managing their diabetes symptoms and/or progression. They may know it's to treat diabetes but hasn't made a link with their day to day symptoms. Use of a **key/lock metaphor***[3] and **fuel in the engine*** to explain the action of insulin in relation to symptoms.

The purpose of blood glucose testing

The patient does not understand how collecting data may benefit them. They might think it's for your purposes only or they might have a 'one size fits all' idea about insulin doses. Using a **bespoke tailoring*** analogy and **emerging patterns*** diagram to explain dose titration.

Insulin and weight gain

The patient is concerned that they will put on weight. There may be some unhelpful assumptions tied to this: 1) the insulin makes them hungry 2) the insulin makes them put on *extra* weight 3) the weight will be ongoing. Using a **weight gain plateau***[4] graph and a discussion related to weight being related to consumption rather than 'extra' calories. Discussion points may include only putting on what you consume; ways to manage weight gain, weight gain reaching a plateau.

[3]* See Appendix

D-6 Handbook V2

Working with unhelpful thinking styles

The next section provides some 'psychoeducation' rather than diabetes education. It introduces ways to help restructure the information which may have got distorted due to cognitive bias (i.e. an unhelpful thinking style). This section considers ways to help patients *think* in a more healthy way about their diabetes.

Personalising

If a patient tends to attribute all negative outcomes to themselves it is likely that they will start to feel bad about themselves, experience excessive distress in response to their diabetes management and possibly give up. For these patients there is too much responsibility on their shoulders. Too much attention is given to the factors they can control and not enough attention is given to the factors beyond their control. They feel fed up because their efforts aren't translated into results and this gives them an overall sense of failure or not being 'good enough'.

Using a **Spider diagram*** (for blood glucose control and for weight - see Appendix) is one way to re-focus a patient's attention on the multiple factors that influence a health outcome.

Key points in using this visual aid:
Draw it out if possible on a blank piece of paper. Start with the blood glucose/weight circle in the middle. Ask the patient to come up with all the factors they know that influence this reading. Try and reach a blank with the patient. Ask for permission to complete the diagram if any are missing. Key questions: What are within your control and what are less easy to control or outside of your control? Make sure you check back to see if and how this new piece of information may have altered their perspective.

Example

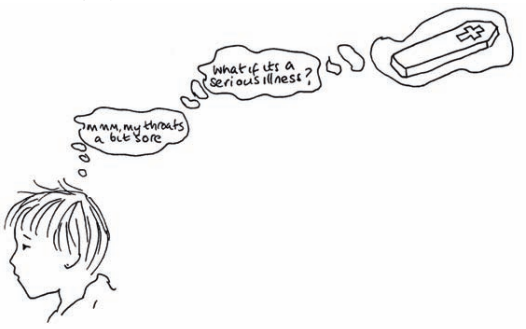
C: Would it be ok to look at what affects your blood glucose in more detail?
P: Ok
C: If this is a blood glucose reading in the middle, what would you say are the factors that will influence this number?
P: Erm well what I eat obviously and when I've taken my insulin and how much.
C: Great – so I'll write here 'food' and 'insulin'. What else?
P: If I've done lots I suppose – been rushing around y'know.
C: OK, so 'level of activity' (writes this down). What else?
P: Erm … dunno … that's it isn't it?
C: Might there be anything else that can cause your blood sugars to go up or down?
P: I suppose if I've been ill
C: Yes so 'illness' is another one. What else?
P: Can't think anymore
C: Can I add some more to this picture?
P: ok

D-6 Handbook V2

C: We know that 'stress' can affect your blood glucose readings, also your 'hormones' – where you are in your menstrual cycle. And your 'genes' will also affect this – so some people will respond better to insulin than others. What are your thoughts about that?
P: Yeah, I sort of know that but I guess I don't really think of those things on a day to day basis. There's a lot going on really isn't there?
C: Precisely. What factors are within your control?
P: These ones (points to food, insulin, exercise)
C: What factors are outside your control?
P: I guess these ones (points to the others)
C: So what might that say about why your readings are sometimes disappointing despite your best efforts?
P: Well there's all this stuff going on all the time. Some of which you're probably not even aware of … like whether you're coming down with a cold or not noticing you're stressed.
C: Uhuh. Your body is a complex processing machine – trying to juggle all these variables.

Catastrophising

If a patient tends to focus on the worst case scenario they may be feeling overly anxious in response to diabetes cues. Very often a high arousal state will mean that the most threatening outcomes become highly salient and the less severe outcomes are neglected. With this thinking style, patients may over-react to low or high blood sugars, driving them in the opposite direction to bring down their anxiety. In addition, some patients may find the anxiety so overwhelming that they cope through avoidance.



A useful analogy for these patients is to think about the function of fear. Fear can be protective e.g not jumping off a cliff or not putting your hand in a fire, but it can also paralyse us when it goes into overdrive e.g. preventing us from going to a job interview. In this case, fear is not helpful anymore. Another useful analogy is to relate their diabetes worry to a guitar string – it needs to be neither too taut nor too loose for optimal self care. Therefore, some worry is understandable and helpful to keep us safe – too much can be damaging and unproductive. The concept of **healthy and unhealthy fear[5].**

For these patients, it will be important to draw out the *cumulative* nature of risk. Useful discussion points are that there will be mild hypos as well as severe hypos, that

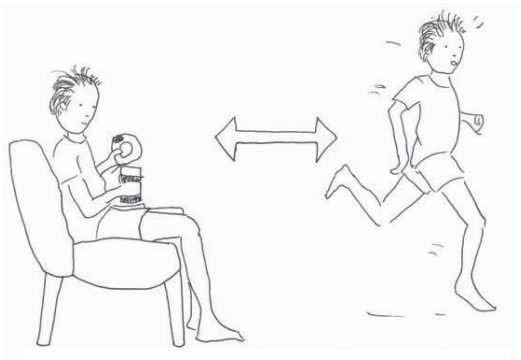
[5] See Appendix

D-6 Handbook V2

complications are related to ongoing raised blood glucose levels as opposed to occasional readings and that not all complications are life threatening.

All or nothing thinking

Patients who have an 'all or nothing' thinking style may not attempt any sort of behaviour change, unless it can achieve 100% success. This may mean they avoid trying anything or give up at the first sign of a lapse. They generally hold high standards and find it hard to tolerate anything less. Paradoxically, patients who appear to not care about their diabetes may actually hold this thinking style. The thought of not doing a 'perfect' job causes intolerable disappointment and/or anxiety. Their response patterns can be quite rigid i.e. it has to be done this way and no compromise is possible. They may be somewhat of a perfectionist.



From one extreme to other

This attitude can be very unhelpful with diabetes. This is because managing diabetes is all about managing setbacks, unexpected results, outliers etc. Your response to when it goes wrong (rather than when it goes right) is a key indicator of successful management.

There are some psychological tools that may address the issue of 'all or nothing' thinking. The **perspective taking graph** (see appendix) demonstrates that the path to improvement can be a bumpy ride. This can apply to weight loss as well as glycaemic control. The idea is that the person is continually improving (the dotted line) but at any one time can be experiencing a lapse (solid line). It is at the point of a lapse, that we may lose sight of the bigger picture, lose hope and give up (the magnified area). The danger is not the lapse, but the patient's *reaction* to the lapse.

The **self defeating cycle**[6] diagram can be drawn out with the patient for a variety of different behaviours. It demonstrates how high standards can drive change, but are not so helpful in managing lapses. At the lowest point in the cycle, patients attempt to get back on track by setting themselves another high standard and thus get caught in a vicious cycle. The diagram illustrates the need to allow for some 'slack' in the system in order to bring about realistic and sustainable change.

[6] See Appendix

D-6 Handbook V2

Addressing health beliefs – HOW to do it

Identifying health beliefs
Use gentle persistence when looking for health beliefs. You may need to phrase the questions differently, several times, to uncover a patient's true understanding of their illness and how to manage it. You may find it helpful to think about different thoughts as layers of an onion and that the 'arrow questions' allow you to peel back the layers, until you reach a key belief. Try not to give up at the first hurdle, remember that patients may not be used to exploring or expressing their beliefs, and therefore some gentle direction may be needed. If the behaviour doesn't make sense to you, keep going until it does.

P: The dietician says I need to eat less rice and potatoes
C: Why might that be a good idea?
P: It'll help my diabetes

The patient knows they need to eat less carbohydrate, because it will help their diabetes, but they're still not doing it, therefore their behaviour does not make sense to the clinician, so they keep going with their line of enquiry.

C: How might that be?
P: Well I suppose I might lose some weight but I'm happy as I am you know. My husband thinks I look fine.

So the patient has only linked dietary changes to weight loss and not the progression of diabetes. Furthermore, the patient does not even view weight as an important issue. Consequently, the non adherence to dietary advice now makes more sense.

The upward or downward arrow needs to be used sensitively, otherwise there is a risk of it sounding like an interrogation or knowledge test. Speak with a gentle tone of voice and express genuine curiosity about a patient's viewpoint. It can be helpful to preface your questions with phrases such as:

"I'm really interested in your take on this .."
"People interpret health information in all sorts of different ways …"

Beware of a tendency to make assumptions (see more about this in the 'Hotspots' section below). Follow a line of enquiry with a patient, rather than jumping to predefined conclusions. The common thinking errors in diabetes table, is merely a guide to inform your questioning, not a substitute for asking the patient.

D-6 Handbook V2

Creating new health beliefs
The most important part about providing new information is to check back with the patient. A useful sequence for medical consultations is:

Elicit – Provide – Elicit

This means asking about what the patient has understood (*elicit*), providing information to address the gaps or misunderstandings (*provide*) and then checking back with what the patient has taken in (*elicit*). Never assume a patient has heard what you have told them. Some useful questions:

What does that mean to you?
How does that sound to you?
What have you heard from this?
What might you take away from this?
What's the take home message?
How would that fit with how you see things?
How do you see things now?
How does that change how you view things?

Notice how all of the above are open questions. This avoids the closed question trap:

C: Does that make sense?
P: Yes
End of consultation

Open questions are much more likely to identify potential areas of misunderstanding.

When using the visual aids in the appendices (e.g. blood glucose spider diagram), it is usually more constructive to draw them out live in the session rather than using a photocopied template. Firstly, this helps to keep the patient's attention as they watch an unfolding picture emerge. Secondly, it gives the patient more time to process each part of the diagram as you draw it out. Thirdly, it allows you to use the patient's own words. A ready made template is far less engaging for the patient.

When you present new information which challenges old beliefs this can be threatening for the patient e.g. *I've spent all my life trying to control my diet and now you're telling me I'm too much of a perfectionist*. Rather than presenting new information as the 'gospel truth' or the only way to view a situation, present it as a hypothesis, an alternative. e.g.

A common worry is …does this make sense to you?
Some people find that thinking about it in this way helps ….
It can be confusing when you've approached things in a certain way for most of your life, but I wonder if you might consider an alternative ….?

D-6 Handbook V2

Addressing health beliefs – clinician HOTSPOTS

But I know why they're not taking it, it's obvious …I wouldn't want to swallow huge Metformin pills / inject myself 4 times a day

Putting ourselves in the place of the patient can be useful in evoking empathy, but it can also leave us quite stuck or alternatively barking up the wrong tree. The obvious reasons to you may not be the reasons that are most significant for the patient. Furthermore, patients may actually put up with quite a lot if they believe it's in the interest of their well-being. Consequently, it may be a health belief which stands in the way of behaviour change, rather than the practical obstacles of tablet size and injection regimes.

African people are less concerned with their weight

You may have never thought the above, but the point being illustrated is that it is tempting to make assumptions about our patients. The human mind is often drawn to spot patterns and make stereotypes. This could be helpful in situations which require quick and decisive action and where we don't have time to analyse each individual situation. However, in behaviour change work, these assumptions are problematic for many reasons: 1) they prevent us from engaging with the patient's individual story and the possibility of exceptions 2) it shuts down creative thinking or problem solving 3) it can often leave us feeling quite helpless or stuck in a situation. In behaviour change work, it is often the exceptions rather than the rule which bear more fruit.

But they might have a hypo … that's not a distortion!

There are some very real risks involved in having diabetes. However, some patients manage to live with these risks more successfully than others. One factor which will influence this will be how they *evaluate* that risk e.g. are they viewing all hypos as severe (catastrophising) or do they feel having a hypo means they are weak or have failed (personalising) or do they feel they need to avoid all forms of exercise (all or nothing)? These questions are important because they will influence the *amount* of distress one patient will feel compared to another patient, faced with the same risk factor.

It's not the fact that the patient might have a hypo which is the distortion but the subtle nuances regarding severity, frequency, responsibility and action which may be distorted. The downward arrow technique allows you to move beyond medical facts to personal interpretation. This is where you have room to manoeuvre.

Common unhelpful thinking styles in diabetes

Thinking style	Definition	Maintaining thoughts	Unhelpful behaviours
Personalising	Attributing all negative outcomes to a personal deficit, often neglecting the role of other factors	*I don't want you / me to see a bad result* *I am my results* *I've failed* *I'm sure other people can manage this better than I do*	Not testing/recording blood glucose levels regularly
Catastrophising	Exclusively focussing on the worst case scenario	*I will have a hypo* *I will get complications*	Deliberately running sugars high / low
All or nothing / Black and white	Responses are on either end of a continuum	*If I can't do it perfectly I might as well give up* *There's no point trying I'll never get it right* *I'll have to test every day of my life*	Yo yo lifestyle changes e.g. diet, smoking, alcohol
Discounting the positive	Exclusively focussing on what has gone wrong/is negative	*Nothing is working!* *Everything I try goes wrong* *I'd be better off having cancer*	Passive / aggressive in consultation
Overgeneralisation	Applying one case example to a whole group	*My friend ….and she's ok / has complications* *I didn't make it the last time I tried to diet/ give up smoking* *I'll put on loads of weight*	Any of above behaviours
Subjective reasoning	Drawing conclusions from feelings alone	*I feel ok, so I don't see the need for medication* *My body tells me when I'm low/high* *I know myself better than a machine* *I feel worse when my HbA1c is lower*	Poor medication adherence Not testing/recording regularly

Chapter 6:
Shaping Behaviour

D-6 Handbook V2

Skill 6: Shaping behaviour

Why is shaping behaviour important?

So far we have been considering the skills that help our patients move towards a position of *wanting* to make a change in their life. Once a patient feels ready for action, it can be tempting to think that the work is done. However, the process of change will present the patient with a number of challenges: the risk of failing, the risk of getting it wrong, the risk that other people will react negatively and/or that they will judge themselves negatively. In one way, the work is just beginning. Patients may fall at the first hurdle without adequate preparation, encouragement and support to manage set backs. Consequently, the main focus of this chapter is how to shape patient behaviours towards a positive outcome.

The key principles are:

- Setting realistic goals
- Encouraging experimentation
- Managing set backs

D-6 Handbook V2

Shaping behaviour – WHAT to do

Goal setting

Setting goals with a patient serves several functions. It helps break the task down into manageable steps, it gives the patient defined markers to aim for and it is an opportunity to ground any fantasies before they take flight (e.g. I can only be happy as a size 0 supermodel). In brief, you are setting the patient up to succeed.

A useful acronym when goal setting with a patient is to make **SMART** goals. There are several variations of this acronym, this is one of them:

S **Specific**
M **Meaningful**
A **Attainable**
R **Rewarding**
T **Time based**

(S)pecific
The following questions can be used to help the patient pinpoint exactly what they are aiming to achieve and setting tangible markers for achieving this.

What do you want to specifically achieve?
When will you feel able to try this?
How will you attempt this?
Which way will you try and make this change?
Who will be involved in you meeting this goal?

> *P: I'd really like to get in shape*
> *C: That's a very positive goal for your health*
> *P: Yeah I know*
> *C: We often find people are more likely to succeed if they have really prepared themselves to meet the challenge. May I ask you a few questions about how you might tackle this?*
> *P: OK*
> *C: When you say "get in shape" – what would you like to specifically achieve?*
> *P: I'd like to drop a few dress sizes*
> *C: So "a few" being ….?*
> *P: Say 2*
> *etc*

(M)eaningful
The goal must be meaningful i.e have some value for the patient. Encourage the patient to be explicit about the value of their chosen course of action. This builds on the MI skill of eliciting change talk (Chapter 3). Once again, according to Bem's theory of self perception, if a patient hears themselves articulating the reasons for change, they are more likely to act upon them.

D-6 Handbook V2

Why have you chosen this particular goal?
If you succeed, how might your life be different?
How might your friends / family / healthcare professionals view the change?

(A)ttainable
The goal must be realistic. This is an opportunity to check that the patient is not setting themselves up to fail.

Does this feel like a realistic goal to you?
What would be a more realistic goal?
Do you feel you have the resources to achieve this task at the moment?
Might it be possible to break it down further?

(R)ewarding
Behavioural psychology teaches us that attaching a positive incentive to a behaviour is more likely to result in that behaviour occurring. Patients can become disheartened if they do not see rewarding results for their efforts. This can be particularly challenging in relation to long term changes, where the benefits are not immediately apparent e.g giving up smoking, or achieving sustainable weight loss.

How can you make this task rewarding for yourself?
How might you reward yourself?
How will you know if the change is working?
What are the positive signs to look out for?

(T)ime-based
The patient has set a realistic time frame to achieve their goal.

Over what time period can this goal be achieved?
Will you need more / less time to tackle this?

Playing devil's advocate

This involves thinking through with the patient how this goal will be met and what might get in the way. The purpose of the conversation is to prepare a patient in advance so that they don't have to come up with solutions at their most vulnerable time (i.e when things have gone wrong). Some questions might include:

What might get in the way of achieving your goal?
How might you address this barrier?
What will help you remember?
When you're feeling down, what will help you stay motivated?
What people in your life could help you achieve your goal?

D-6 Handbook V2

Using a graded hierarchy

If a task is particularly challenging for a patient e.g. injecting/testing when they don't like needles, break the task down into small but cumulative steps.

Climbing the mountain worksheet (see appendix)

This is also a particularly useful technique for patients who are suffering with anxiety and/or depression. For these patients, relatively simple tasks may feel overwhelming, thereby lead to avoidance. Helping these patients to view the task in small manageable parts can encourage them to start moving forward.

Anxiety management

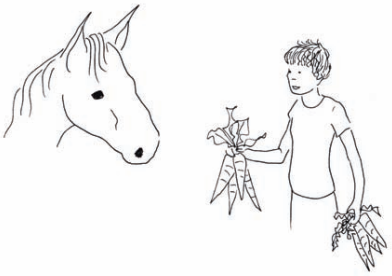
Anxiety can prevent patients from making healthy changes (e.g. testing their blood glucose levels, walking into a new gym, visiting the doctor) and it can also maintain unhealthy behaviours (e.g. smoking, drinking, not thinking about diabetes). Teaching patients basic relaxation skills can help patients approach anxiety provoking situations.

Controlled Breathing (see appendix)
Progressive Muscle Relaxation (see appendix)
Distraction (see appendix – using senses)

Patients may find they are plagued by persistent worry e.g. about complications, having a hypo, having a heart attack. These concerns are usually grounded in reality for the diabetic patient. The task is not to eliminate the worry since it is appropriate that the patient has some level of concern about these issues, but rather to make it a less intense. The following tools can help with this:

Healthy v unhealthy fear (see appendix)
The worry tree (see appendix)
Coping with uncertainty (see appendix)

Using rewards



Behaviour can be shaped through positive reinforcement i.e. praise and rewards. Very often patients don't reward themselves because they think they don't deserve it or their focus is on what they haven't achieved as opposed to what they have (discounting the positive). This especially prominent in depressed patients. Rewards can provide a strong motivational pull to continue the good work. It can be useful to explain to patients that in psychological terms,

D-6 Handbook V2

changing behaviour is more successful when it's linked to an incentive (see SMART and (R)ewards section).

Of course coming to see an understanding and supportive clinician is also a reward in and of itself and should not be underestimated as a powerful mediator of change. Talking about rewards shows the patient that you think their behaviour is worth rewarding. You're also acknowledging the work that has gone into the change. After all if it was easy, they would have made the change years ago.

Diary and reward chart (see appendix)
Pleasant events list (see appendix)

Focussing on increasing self-care activities can also improve mood. This means it can be a helpful intervention for patients who are depressed. However, there can sometimes be a lag between increased activity and improved mood, in the same way, there might be a lag between starting exercise and weight loss or taking medication and HbA1c i.e. there is a *delayed* reward. The following diagram can be useful in explaining the importance of persevering in the absence of immediate, positive feedback.

Activity and mood graph (see appendix)

Problem solving

The path to change is often fraught with obstacles. When a patient hits a road block, it really tests their problem solving skills.

e.g. *When my daughter is ill, I tend to forget my medication*
When I eat out, my diet goes out of the window
The exercise prescription hasn't come through from my GP yet

Good problem solving skills will help patients move beyond the obstacles and will support their sense of self efficacy. The following steps can be useful:

1) Ask the patient to brain storm all the options to overcoming the problem, no matter how silly they sound
2) Weigh up the pros / cons of each option
3) Select upon one option (reinforcing that this is an experiment)
4) Encourage the patient to try it out and report back

C: When there are other priorities in your life, it can be difficult to put diabetes at the top of the agenda
P: Exactly
C: This is a barrier to you taking your medication as consistently as you would like.
Might we use the session today to think about some ways forward …

Again if patients are suffering with anxiety or depression overcoming obstacles can present a significant challenge. Impaired concentration and memory can affect a person's problem solving abilities and low mood can diminish a person's confidence in

D-6 Handbook V2

being able to handle those problems. Consequently, helping patients develop problem solving skills is very relevant to this population.

D-6 Handbook V2

Shaping behaviour – HOW to do it

How you talk about the process of change is very important. Encourage the patient to view any step they take as an "experiment" – a try it and see approach. In this way, there is no pressure to make a permanent commitment and the patient is more likely to try out a new behaviour.

Normalise the occurrence of set backs. This cannot be overestimated. Patients are vulnerable to relapse when their plans don't run smoothly. If they are prepared in advance, they are more likely to use set backs constructively. You can normalise the presence of set backs, by talking with patients about set backs during goal setting i.e. how they might manage them *when* not *if* they occur.

Secondly, when set backs do occur, they need to be managed sensitively, as the patient may be judging themselves harshly or expect you to be disappointed in them. This may even lead to them no longer attending appointments. When a patient attends an appointment after experiencing a set back, this provides a natural opportunity for affirmation:

> *C: well I'm really impressed you still came along to see me today even though you don't feel you have 'good' news to tell me*

Again, let the patient know that although they are feeling frustrated, what they are going through is part of the normal process of change. The use of the following visual aids can be helpful here:

> **Perspective taking (see appendix)**
> **Spirals diagram (see appendix)**

Useful phrases to help patients deal with set backs can also be helpful. This is called positive self talk e.g.

> *There is no such thing as failure, only feedback*
> *The path to success is a bumpy road, not a straight line*
> *I'm allowed to make mistakes - it's how we learn*
> *There is always an opportunity to have done things better, but there's also an opportunity to do things worse.*

The CBT skills of shaping behaviour need to be combined with the spirit of MI. Always check what resources the patient already has. The skills presented in this chapter are merely tools, and you may not need to use any of them, if a patient has already found a way to overcome obstacles e.g.

> *P: If I'm getting anxious about my injections, I just remember I want to be around for my children and that gets me through.*

It would be inappropriate to introduce anxiety management techniques without enquiring how the patient is already coping and whether this is working for him/her. If you feel that the patient is genuinely lacking in resources or missing vital information,

D-6 Handbook V2

then it is ok to provide this. However, once again, always ask for permission before giving advice or making suggestions and check back with the patient, using the 'elicit – provide – elicit' sequence.

Intellectual property of King's College, London. Do not reproduce without permission. V2.

D-6 Handbook V2

Shaping behaviour - clinician HOTSPOTS

It seems tedious to go into this much detail

It is important to check exactly how a patient will go about changing their behaviour. By examining the minutiae of their plan, you and the patient can see where the pitfalls will be in advance. This means you can plan for these obstacles before they happen. Preparing patients for change is just as important as getting them to the point of wanting to change. The former is often neglected, risking that good intentions fizzle out.

I thought I was home and dry with this patient

Reaching the action stage, can feel like a significant landmark. You have worked hard to help the patient process their ambivalence and reach a point where the patient is starting to make changes. It can be utterly dispiriting when patients start to falter with their good intentions. Remember this disappointment will be felt by the patient as well as you, even if it is unexpressed. It is just as important to prepare *yourself* for set backs, as well as the patient. Keep in the forefront of your mind that lapses are normal, as opposed to abnormal and a sign of defeat. By not over reacting to them, you demonstrate that backward steps are to be expected and are surmountable.

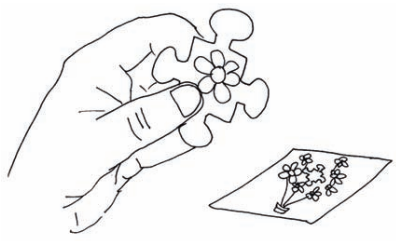
But I'm not a Psychologist!

Basic mood/anxiety management can be carried out by other health professionals. Indeed, it can make more sense sometimes for the patient to do this work with the person they have built a relationship with rather than being referred on to a stranger. A few basic suggestions/instructions in managing low mood or anxiety can make all the difference between a patient trying out a new behaviour and giving up. Remember that in cases of extreme distress, it is always possible to refer on to a specialist mental health professional.

Section B:
Integrating the skills

D-6 Handbook V2

Integrating the skills



So far we have talked about individual skills to promote behaviour change. This chapter considers how to weave the skills together. Remember that a patient's stage of change may vary from week to week and even within a single session. Therefore, it is important to use these skills flexibly, adapting them to the shifting needs of the patient.

The overall attitude

It is common to focus on specific techniques when first learning a new methodology. Indeed, this is how this handbook has been structured. However, the overall spirit or attitude of the clinician is more important than getting the 'right technique'. This is because there may be more than one (MI congruent) way to approach a specific situation. Consequently, the underlying 'spirit' of MI should dictate how we proceed rather than being bound by technique. Furthermore, the techniques themselves will flow more comfortably, if the clinician has adopted a particular mindset. This mindset assumes the following:

i) The patient has the answers
ii) The patient is in two minds i.e. part of them wants to change
iii) Resistance is useful information

Beginning

Starting the intervention

The patient will have been told about participating in a trial already. This provides the first opportunity to provide an affirmation i.e. acknowledging their contribution to research and willingness to try a different approach. You may consider the following example as a guide to introducing the research:

> *"Thank-you for enrolling in this study. We recognise that managing diabetes can be a difficult and challenging task.*
>
> *The purpose of these sessions is to support you in getting your diabetes control as good as <u>you</u> feel you are able to.*
>
> *Although we have some expertise about diabetes, we recognise that you are the expert about your life and how diabetes fits into it. Therefore, these sessions are <u>not</u> about me telling you what to do. In this way, these sessions might feel quite different to other appointments you've had with a practice nurse.*

D-6 Handbook V2

> *Instead, we will use these conversations to think about some of the difficulties around diabetes self management and what options might exist to help you move forward with your diabetes.*
>
> *There will be 12 sessions in total, but the first six will be face to face for half an hour each.*

Remember that all participants will have had to sacrifice something (time, resources, and energy) to participate in the study. Acknowledge this in the first phase of the intervention e.g.

> *"I am impressed that you have gone to the effort to come and join this project. You have had to get time off work/arrange child care/ prioritise your health over other activities etc, to get here today. This shows commitment to approach your diabetes in a new way and is a good place to start."*

Try to avoid the use of terms such as *random*, *trial* and *motivational interviewing* as they can be open to misinterpretation. Instead, consider talking about the *study*, the *research*, your diabetes *meetings* or *project*. Similarly, try to avoid overly simple statements such as *good* or *bad* control. Such phrases contain an implicit moral judgement about the patient i.e. that they are good or bad, thereby presenting the clinician as judgemental. Consider more neutral language e.g. *tighter* control, a *lower* HbA1c.

Starting an individual session

The aim of the beginning of a session is usually to establish rapport and then to set a focus. As we considered in Chapter 1, you will be using your OARS to express empathy and genuine interest in their perspective, thereby facilitating a therapeutic rapport. In the early phases of a session / intervention, the patients should be doing most of the talking. Your role will be to show that you've understood what they've said and are on their side.

Using a menu sheet (see appendix) can be a good place to start. It describes most of the factors that influence diabetes control. By asking patients to tell you which areas they may need to work on, you achieve several aims:

i) To identity whether the patients understanding of what needs to be tackled is the same as yours.
ii) You demonstrate to the patient that you are interested in their perspective and don't have a pre-determined agenda
iii) It provides a natural opportunity for patient's to expand upon their reasons/barriers for change.

If the patient chooses more than one area, ask them how they would prioritise these areas. If the patient has chosen an area which seems less important for their diabetes management (e.g. exercise rather than taking their insulin). You have a couple of options:

D-6 Handbook V2

1) Ask permission to explain why you would consider insulin a greater priority. Check their understanding of your rationale using the '*Elicit-Provide-Elicit*' strategy

2) Go with the patient's agenda. You can use success in their chosen area as an opportunity to apply transferable skills.

Which option you choose will depend on your clinical judgment. Look out for how engaged/motivated a patient appears by listening out for resistance. With a less engaged patient you may choose to go with their agenda. Where you feel there is a stronger rapport with a patient i.e. they are more engaged, you may decide to offer an alternative agenda.

Consider this first phase as fact finding. By the end you want a really good understanding of the drivers and barriers to change for this patient. That is your only task. Along the way, you might discover some inaccurate or unhelpful beliefs, and where some education might be needed. Remember you don't need to tackle this straight away. For example, you may choose to make a mental note of health beliefs that need to be changed and come back to them later, especially if the patient seems particularly bored, irritated or angry. On the other hand, if they appear very anxious/despairing, you may find it a useful time to provide some correct health information. However, always ask permission first.

Your main goal at this stage is that the patient will return to the next session. Patients that have struggled with their health may be low in motivation and the use of text/phone reminders can be helpful in keeping them engaged with the study. At the beginning of the next session, you will want to gauge the 'motivational temperature' of the session. The following questions can provide a useful starting point:

What do you recall from last week?
What were your thoughts about what we spoke about last time?
How relevant does this area feel for you today?

Midway

The middle phase of a session/intervention is usually where you start to look for and amplify pro change talk. You will be using your '*eliciting change talk*' and '*supporting self efficacy*' skills. You hope to evoke some forward momentum. The pace and goal of this momentum must be in tune with the patient's capacity of change. Going too fast may risk losing a patient or producing temporary but not sustainable change. In addition, setting yourself unrealistic goals for a patient, may affect your own levels of frustration and job satisfaction.

A key indicator for pace is resistance. Consider resistance as your friend – when a patient starts to resist e.g. not saying much, becoming defensive or offering lots of anti change talk, it is a sign to take your foot off the accelerator for change. Go back to *reflective listening* and see if there may be room to manoeuvre in a different direction (more on this in next chapter 'Trouble Shooting').

D-6 Handbook V2

A key indicator for what is a realistic goal will be the patient's position on the change cycle. If a patient is in 'pre-contemplation', a goal for the clinician might be to move them towards 'contemplation'. Similarly, if a patient is in 'contemplation' the next realistic step may be 'preparation'. Note that in neither of these cases is the goal 'action'. Remember that behaviour change isn't just about concrete actions. Doing behaviour change work is also about promoting change in *thoughts* and *feelings* which scaffold or provide the foundations for action. The table below summarises how different stages of change may direct you towards different tasks in the session.

Stage of change	Task
Pre-contemplation	*When patients are in this phase, they may not realise they have a problem or feel very defensive about approaching it.* Key tasks are to express empathy i.e. reflecting back the difficulties and to *gently* develop discrepancy i.e. eliciting from them reasons for change. Another task is to avoid argumentation! Key skills: OARS; DARN; double sided reflections, overshooting reflections The main goal is to encourage the patient to start to take an interest in their health.
Contemplation	*The patient realises there is a problem, but is not ready to take action.* Key tasks are to elicit pros/cons for change and to amplify the pro-change talk. Key skills: OARS; DARN; amplification questions The main goal is that the patient starts to view change as the more appealing option.
Preparation	*The patient is thinking about change, but has not taken any steps yet.* Key tasks are to support self efficacy and express empathy regarding any concerns or anxieties. Key skills: OARS; CAT; solution focussed questions; resisting the righting reflex The main goal is that the patient starts to believe they can make this change i.e it seems achievable

D-6 Handbook V2

Action	*The patient is taking practical steps to make health related changes. Without appropriate acknowledgement patients can fall back a stage*. Key tasks are to express empathy for the effort, sacrifice, resourcefulness needed to make this change. Also to elicit change talk about why these actions may be beneficial. Key skills: OARS; amplification questions; affirmations The main goal is to stop and note the achievement and not rush on to the next task.
Maintenance	*The patient is making consistent changes. The patient may start to become weary of the effort required to maintain the change or worry how long it will last.* Key tasks are to elicit change talk about why these actions are useful/beneficial. To problem solve with the patient about what could get in the way and to support their self efficacy in thinking about solutions. Key skills: OARS; playing devil's advocate; using rewards; problem solving; set back management The main goal is to prepare the patient for setbacks and potential strategies to start moving forward again.
Lapse	*The patient has gone back to old habits, after starting to make changes.* Key tasks are to express empathy about any disappointment, regret they may be feeling. Also to normalise the presence of setbacks and to support self efficacy in moving forward again. To acknowledge where they have got to. Key skills: OARS; affirmations; solutions focussed questions, setback management The main goal is for the patient to put their lapse into context (i.e. a temporary setback) and to develop the momentum to move forward again.

The above table is merely a guide to working with patients at different stages of change. Throughout all the phases, you want to consider if there are any unhelpful health beliefs that are preventing change, especially in the 'pre-contemplation/contemplation' phase. Use your resistance barometer (i.e. your sense of how engaged the patient is) to deliver health education when the patient is likely to be most receptive to it. In the preparation/action phase, you can make more use of the 'shaping behaviour' skills e.g. anxiety management, problem solving, using rewards.

D-6 Handbook V2

Ending

Ending a session
Ending sessions on time is an important skill. It may feel difficult to keep to time when you are working in this psychologically informed way. However, good time management is important for the patient, the next patient (in the waiting room) and for your own preservation. Some practical tips:

- Aim to finish 5 minutes early. This 5 minutes is usually always taken up e.g. sorting out the next appointment time, walking them to the door, saying good bye
- 10 minutes before the end, be mindful of drawing the session to a close
    - Avoid opening up complex topics during this time
    - Use summaries to signal the session is winding down
- Ending questions:
    - What would it be helpful to take away from today?
    - What might stay with you from today's session?
    - How does that fit for you? (after you've given a summary)

The above ending questions are ways to gently explore where you have got to by the end of the session. They should not be used as inadvertent 'goal setting' questions. Remember that pushing patients towards goal setting before they are ready (ie. in 'Action' on the stages of change) will risk increasing resistance.

It can be difficult to end a session when you don't feel you have got to where you had wanted. In these cases, it is tempting to extend the session or to push the patients just that little bit further towards 'action'. Instead, try and view your work as sewing seeds – some green shoots will appear in the session but others will take time to mature during the weeks/months ahead. Remember the spirit of dancing rather than wrestling with the patient, and staying close to where they are on the cycle of change. This will require some patience.

After your session, it is advisable to make some notes to aid your memory. The following headings can be helpful:

Review – life events e.g. doctors appts, child starting school, dog died
Progress – what has gone well re. diabetes care
Difficulties – what areas have gone less well re. diabetes care
Support – what support you offered the patient affirmations; pros/cons of change etc.
Plan – what you and/or patient plan to do before you next meet

D-6 Handbook V2

Ending the intervention
As the intervention comes to an end or the sessions become less frequent, consider preparing the patient for this transition. In practical terms:

- Make the boundaries of your contact explicit. When it will start, end, how long each session is and who they can contact between sessions.
- Count down your sessions - "today is the second session out of four" etc.
- Consider what support a patient has outside the surgery to continue supporting them with behaviour change (e.g. a supportive friend, buddy, counsellor, befriender, gym, walking group, diabetes patient group etc.)
- In the last few sessions, the skill of 'Supporting Self Efficacy' will be very important. Encourage patients to come up with their own solutions and offer recognition and affirmations for any strengths/resources they use.
- If the patient is in 'Action' you may want to consider using a 'Change Plan' (see Appendix). This is a way to record their achievements and strategies for staying on track.

Be prepared for setbacks towards the end. Some patients will be more demonstrative about their struggles towards the end of an intervention. This does not mean that your work has been in vain, but rather that the patient is reluctant to let you go! Remember the green shoots that have occurred over the course of the intervention and the skills/resources that the patient has demonstrated.

In a nutshell: The D-6 flow

Begin very gently; be open to what the patient brings and let go of a predetermined agenda. Remember that patient defensiveness may be high at the start of a session/intervention and you need to reduce this first.

Introduce the behaviour change menu (see appendix) to start the process of exploration: what are THEIR thoughts/beliefs/attitudes to their diabetes? You are looking for the drivers and enemies to change – finding where the momentum for change will come from.

Be on the lookout for unhelpful health beliefs and make sure patients have the correct information by eliciting, providing and then eliciting again. Always ask for the patient's permission.

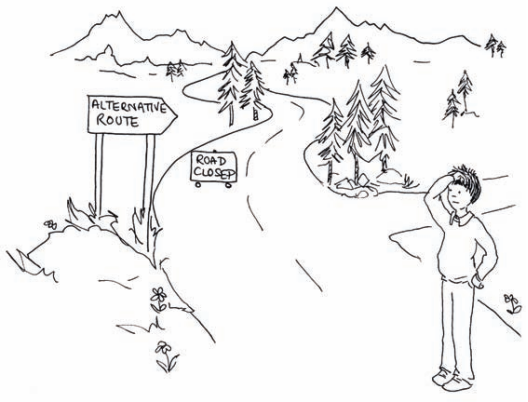
When resistance arises - roll with it; refocus your attention on the green shoots – elaborating and nurturing them. Expect lapses and you won't be dismayed by them.

Keep to time as best you can.

Section C:
Trouble Shooting

D-6 Handbook V2

Trouble shooting



Using the D6 skills may not work for every patient. Remember that these skills increase the likelihood that more of your consultations will be successful, but it's unrealistic to think this will provide a 100% success rate. This chapter deals with what to do when things don't seem to be working. The following are some common dilemmas you may come across:

The patient is attending, but nothing is changing
The patient says the 'right things', but nothing is changing
The patient is becoming more defensive / less engaged

Remember that the above dilemmas represent some form of resistance. When you meet resistance in diabetes (albeit passive) you may feel anxious that you are not doing your job properly. Your patient is not playing the doctor-patient game by the agreed rules. Your offer to provide help and advice is being rejected. You may be tempted to bully the patient and shake them into sense. Or you may feel rejected and want to shrug your shoulders, walk away or label them.

D-6 Handbook V2

Clinician Factors

Before throwing in the towel with a patient take some time to reflect upon your own practice. Below are some of the common traps that can fuel resistance (including passive resistance). We are all liable to fall into these traps from time to time and therefore it is worth pausing to reflect upon how these dilemmas might arise and how we could approach things differently.

A mismatch on the change cycle

This is the most common reason for resistance: the clinician is already in action but the patient is in pre-contemplation/contemplation. Prematurely pushing a patient towards action can result in potential disengagement e.g. a patient may agree to do something, but repeatedly turn up having failed to do the task.

Remember that motivational interviewing is about helping a patient resolve their ambivalence. This might mean that the 'work' is about strengthening a patient's reasons for change through eliciting change talk. In order to do this, we need to move away from the notion that 'action' is the only valuable outcome. The preparation steps are still 'work' and patients can be congratulated for doing the 'thinking' around behaviour change e.g. preparing, researching, weighing up pros and cons, discussing with partner.

The best way to fine tune our practice, is to listen to our patients. Use your recorded transcripts to do this. Our patients are our best *teachers* and will provide a wealth of feedback, if we are receptive to it (e.g. how did this patient respond after what I said?)

Key reflections:
Am I at the same stage of change as the patient?
Am I prematurely pushing them into action?

Not feeling understood

Another common reason patients disengage is because they don't feel understood. Patients in this situation worry that their difficulties aren't being heard and that they will be judged or pushed into a situation they don't feel ready for. In this position a patient may become more defensive or disengage from their healthcare service altogether. Consequently, building rapport through *active listening* is another vital, and sometimes overlooked, piece of work.

We may feel a huge amount of empathy for our patients, and it is easy to assume that by listening and nodding our patients will realise that we understand. However, the skill of 'active listening' involves making your response explicit through verbal statements. *Simple reflections and affirmations* can be very effective in communicating empathy.

Key reflections:

D-6 Handbook V2

Am I expressing empathy?
How does the patient know that I have genuinely understood their position?

Not getting a word in

It is easy to slip into advice giving mode or to ask lots of closed questions to identify a 'solution'. Consider how much space the patient has to think about and articulate their own dilemmas/solutions. Remember *Bem's self perception theory* and the importance of patients' hearing themselves talk. Also remember the subtle messages communicated by 'stealing' this opportunity from the patient (that you are the expert, you have the answers and that they have fewer resources than you). This encourages passivity and dependence. Persevere in helping patients become more creative and self reliant – remember the *3 strike rule*. It can feel like a quick and easy solution to provide the answers, but this does the patient no favours in the long run.

Key reflections:
Am I resisting the righting reflex?
How much time do I give the patient to come up with their own ideas/solutions?

Discounting the positive

If it feels like nothing is changing, is it really true that *nothing* is changing? It may be true that the patient's HbA1c is not coming down yet, but exclusively focussing on this is a surefire way to fuel burnout for the patient and the clinician. Remember that the role of MI is to engender hope. This means looking out for the small successes e.g. coming to appointments, verbalising thoughts about change, trying new things out, making a phone call, discussing self care with partner. With hope in the consulting room there is momentum to move forward.

Conversely, when patients are doing well, it can be very tempting to focus on the next goal, on how things can be improved. But pause here. Allow yourself to expand on the positive narrative: *how did they manage the change; how did they feel afterwards; other people's reactions* – even if this takes the entire consultation. Sowing these seeds of optimism will fuel the behaviour change process when they leave the consultation room. By not fully acknowledging what they have already achieved, patients are then left with the message that they still are not quite 'good enough'.

Key reflections:
Am I giving more weight to what still needs to be improved upon 'vs' what they have already achieved?
How does the patient feel when they leave the consultation – hopeful or hopeless?

D-6 Handbook V2

Buying into hopelessness / the patient story

Sometimes we can become overly 'patient centred'. We follow, empathise and affirm at every consultation. The patient enjoys coming, talks a lot, feels understood - but not a lot is changing. This is particularly true when patients present us with so many barriers for change that we end up feeling as overwhelmed as they do – we are then buying into the patient's hopelessness. Remember that motivational interviewing is both person centred AND directive. Try to include some '*eliciting change talk'* questions in every consultation. By just following the patient we don't give them an opportunity to consider alternative behaviours and fuel the engines for change.

Key reflections:
Am I getting stuck in the patient's story?
Am I neglecting to ask change talk questions?

See Appendix (What MI is not and MI adherent/non adherent behaviours) for more advice about staying on the right track.

D-6 Handbook V2

Patient factors

Re-visiting the dilemmas outlined above:

The patient is attending, but nothing is changing
The patient says the 'right things', but nothing is changing
The patient is becoming more defensive / less engaged

The success of the D6 skills will depend, to some extent, on the competency of the clinician. However, we should not overlook the type of patient we are presented with. There are some situations in which it becomes extremely challenging to use these skills. In these situations we may need to get extra resources (e.g. refer to another service) or to adjust our expectations as to what is a realistic goal. Areas to consider:

Is the patient excessively distressed?
Distress can present itself in many different forms: shaking, shouting, crying or remaining silent. If the emotional temperature is high in the consultation it makes this type of work very challenging. In this situation, expressing empathy (through active listening) can be a helpful response. In addition, avoid effortful questions and keep your statements simple. Very often this can allow the strong emotion to subside.

You may also need to consider the frequency and severity of the distress – is this a brief intense moment in the room or an ongoing problem for the patient. If the latter, you may need to consider a mental health assessment. See Appendix for common mental health problems.

Does the patient struggle with relationships?
Patients may face interpersonal challenges – that is, they may find it hard to trust people e.g. healthcare professionals. They may expect to be put down, hurt, rejected or abandoned because earlier experiences have taught them that people can't be trusted. They might reject or be hostile towards you, pushing you away. Alternatively they may become overly dependent or make demands on you. It is very hard to do this work, unless a patient has at least the potential of developing some kind of therapeutic alliance. Again you will need to seek further support from supervision for these cases. Expressing empathy while maintaining your boundaries (e.g. level of contact) will be very important.

Does the patient have resource limitations?
Consider whether your patient is lacking vital resources (e.g transport, housing, child care, money, intellectual capacity or health literacy). This may affect their ability to attend appointments, to store their medication, to prioritise their diabetes or to understand their health needs. In this case, consider support from other agencies/sources e.g. social services, advocate, carer involvement, use of more visual aids. If their needs are more complex, the package of care should reflect this.

In summary, remember to consider the type of patient you are dealing with and the challenges they face. Use this information to evaluate the appropriateness of behaviour

D-6 Handbook V2

change work at this time. In any situation, you can always rely on your basic communication skills (O-A-R-S) to minimise resistance and find out what the patient wants/needs. However, the goal of improved diabetes control needs to be considered carefully in terms of timing, input from other services and what is a realistic level of change, given the limitations of each patient. Seek supervision for these more complex cases and where necessary refer to other services e.g. mental health; social services; learning disability services. (see Appendix).

